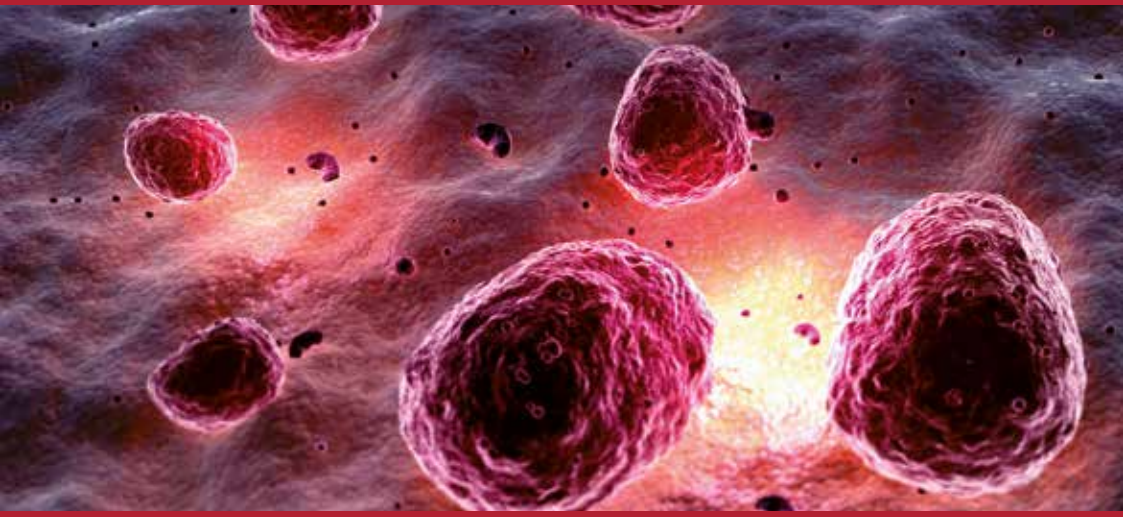
Pomalidomide (Imnovid)

Information for patients and their families

English



Ausgabe auf Englisch

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Picture Figure 1: Dr. med. Jérôme Voegeli

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Content

Introduction

This brochure is for all English-speaking multiple myeloma/plasmacytoma patients in Germany and their loved ones.

It informs about the active substance pomalidomide which is used for the treatment of multiple myeloma and is sold under the product name Imnovid. The active substance name pomalidomide is used in this brochure for easier reading.

What is pomalidomide? How does it work during multiple myeloma treatment? What results can patients expect from the treatment? What side effects can occur?

Important questions the patient should ask before but also during treatment. You will find extensive information about these aspects in this brochure.

This brochure can help

- To better understand the treatment with pomalidomide and
- To decide on one of the currently available treatment options together with your physician.

The therapy with pomalidomide requires your active cooperation to make your treatment as successful, safe and tolerable as possible.

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Immunomodulatory drugs (IMiDs)

Leukaemia and lymphatic cancer (e.g. lymphoma, chronic lymphatic leukaemia and myeloma) are systemic, i.e. the whole body is always affected. For a long time they couldn't be treated at all or only with a chemotherapy – often in combination with an autologous or allogenic stem cell transplantation.

Over the past 20 years new substances have been developed which can be used effectively against cancer, either in combination with chemotherapeutics and/or steroids or alone. Among these new substances there are also the IMiDs, the so-called immunomodulatory drugs or immunomodulatory substances. They block certain growth signals and/or metabolic processes in the tumour cell and at the same time activate the patient's immune system. The term "immunomodulatory" in the narrower sense means "influencing the immune system". Systematic chemical changes of an original molecule, thalidomide, led to the class of drugs of IMiDs. Therefore all IMiDs are similar in terms of structure and their effect on tumour cells. They are all emitted through a safety programme. Due to their chemical similarity to thalidomide it is assumed that they can also have a teratogenic effect. Lenalidomide was the first representative of IMiDs which received approval for tumour therapy from the European Medicines Agency (EMA).

All in all, the new substances have extended the ways of treatment, especially in leukaemia and lymphoma, and are therefore examined further on as to whether they are effective in other diseases as well.

Multiple myeloma

Multiple myeloma, often also called bone marrow cancer, is a malignant blood disease which occurs focally at different sites or diffusely in the bone marrow.

Multiple myeloma originates in the plasma cells which are responsible for producing antibodies in the immune system. At first, the plasma cells develop a malignant neoplasm. These cells then reproduce and form clones (genetically identical cells). These pathologically altered plasma cells all produce the same antibody or fragments of antibodies called paraproteins. These antibodies or paraproteins are unsuitable for the immune defence. In the course of the disease the degenerated plasma cells displace normal cells of blood formation in the bone marrow. The production of working antibodies is obstructed to such an extent that the immune system is weakened.

If degenerated plasma cells appear at several spots in the skeleton, this is called multiple myeloma. If the body shows only one affected spot, the disease is also known as plasmacytoma.

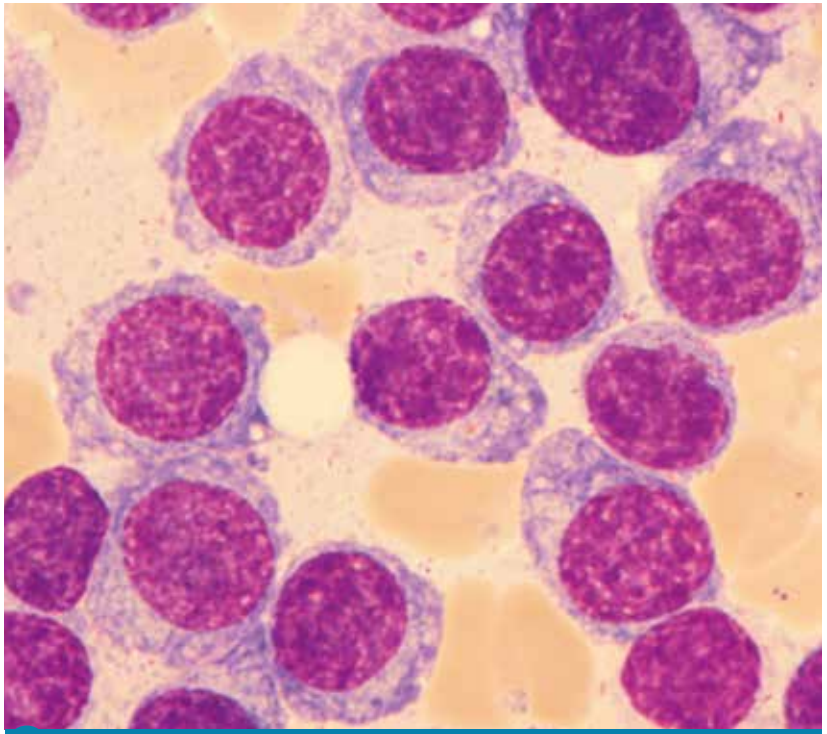
Subtypes of multiple myeloma

Multiple myeloma can be categorised in different subtypes. The categorisation is made on the basis of the antibodies produced, course of the disease and localisation in the body.

The **IgG** subtype is most common (approx. 50%) followed by myeloma with **IgA** release (25%).

Myeloma with **Bence-Jones proteins** which are characterised by the release of free light chains (fragments of immunoglobulins) can be divided into lambda(λ)-chain and kappa(κ)-chain plasmacytoma and occur at a rate of approx. 20 – 25 %.

IgD and IgE myeloma or asecretory myeloma rarely occur. The paraprotein pattern of the disease can change in the course.



1 Malignant plasma cells in the bone marrow

In the case of **medullary** plasmacytoma the neoplastic plasma cells accumulate in the blood-forming red bone marrow. This typically affects vertebrae, ribs, skull, pelvis and the bones of the upper arms and thighs.

The **extramedullary** plasmacytoma can be found in the soft tissue outside the bone, usually in the oropharyngeal space and occurs only in rare cases. In the course of the disease up to 20 % of patients can be affected.

Smouldering myeloma (incidence of approx. 10 – 20 %) must also be distinguished from **symptomatic** (progressive/advanced) multiple myeloma. There are no end organ damages yet such as of the kidneys. Therapy is not indicated. Patients with smouldering myeloma should have frequent follow-ups during the first years of the disease.

The uncontrolled reproduction of the neoplastic plasma cells and the formation of paraproteins with multiple myeloma not only weaken the immune system, but can also result in the dissolution of bone, as well as changes in the blood count and lead to damages of other organ systems such as the kidneys.

Multiple myeloma account for approximately 1 % of all types of cancer and predominantly affect elderly patients. Plasmacytoma can be cured with the currently available treatment methods, but in the case of multiple myeloma only in very few exceptional cases.

Combination therapies in multiple myeloma

In the past years significant advancements have been made in the treatment of multiple myeloma through high-dose therapy followed by blood stem cell transplantation and thanks to the introduction of new substances such as thalidomide, lenalidomide, pomalidomide and bortezomib. These new drugs are used today at different stages of treatment and have contributed to patients now living longer and better with the disease.

In the treatment of multiple myeloma the drugs are in part used alone as monotherapy or in combination with other drugs. In the meantime, there is a large number of possible combinations where new drugs are combined with each other or with one or more standard therapies (melphalan, prednisone, doxorubicin, dexamethasone, stem cell transplantation). The combination of pomalidomide and dexamethasone presented in this brochure is an example of this.

Talk to your physician about all treatment options available to you. Also ask for the reasons for the suggested treatment, possible side effects and the type and duration of the treatment. Additional important questions for your physician can be found on pages 29 – 32.

It is also important that the treatment of multiple myeloma is always adapted to other possible accompanying diseases (e.g. impaired kidney function). Your age, your overall constitution and other conditions additionally play a role for your therapy plan.

The more treatment options there are, the more vital it is for you and your physician to find out together which one is **best for you.**

Maybe you weigh the advantages and disadvantages of a therapy differently than other patients. For this reason you should inform your physician which criteria are particularly important to you for the treatment: for example, a therapy with few side effects, also if it is possibly less effective, or few appointments at the hospital/ doctor's office to allow you to live as normal as possible and enable you to plan a holiday, for example.

How does pomalidomide work?

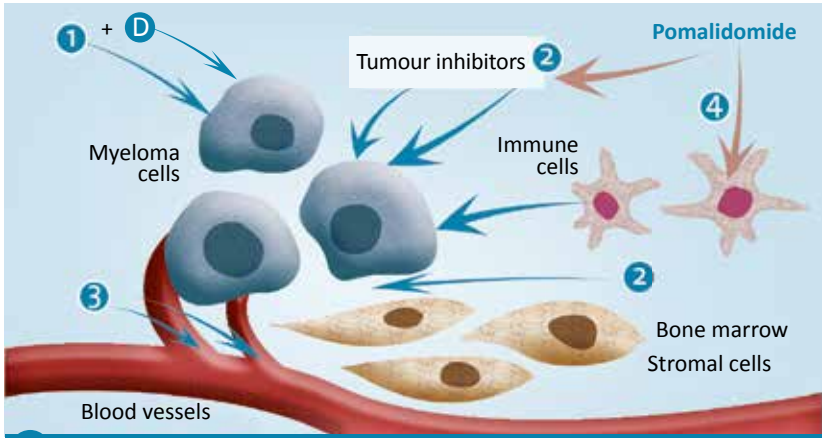
The mechanism of action of pomalidomide has many facets and has not yet been fully understood on the molecular level. The following mechanisms of action of the drug are generally known:

1. Direct attack of the tumour cells: growth stop and triggering of programmed cell death (antiproliferative effect and induction of apoptosis); pomalidomide synergistically acts with dexamethasone (D) and also stops the growth of lenalidomide-resistant tumour cells.

2. Inhibition of the release of inflammatory or tumour-promoting substances, among others through inhibition of the attachment of tumour cells to connective tissue cells of the bone marrow (called stromal cells) as well as an increased release of tumour-inhibiting messenger substances (tumour-toxic cytokines)

3. Inhibition of the formation of new vessels (anti-angiogenesis): The supply of the tumour cells with nutrients deteriorates.

4. Activation of immune cells (T cells and natural killer cells) which also attack tumour cells



2 The different mechanisms of action of pomalidomide in multiple myeloma

How effective is pomalidomide?

The efficacy of pomalidomide in multiple myeloma was proven in one comparative study with a total of 455 patients. The approval of the drug in combination with dexamethasone for the treatment of multiple myeloma is based on these data.

The participants of this study were patients who underwent multiple therapies, on average five previous treatments. The combination of pomalidomide and low-dose dexamethasone was compared with the sole administration of high-dose dexamethasone. In cycles of 28 days the treatment consisted of 4 mg pomalidomide once a day (days 1 – 21) as well as 40 mg dexamethasone (on days 1, 8, 15 and 22) and dexamethasone (40 mg on days 1 – 4, 9 – 12 and 17 – 20). Patients above the age of 75 years received a reduced dexamethasone dose of 20 mg on the days indicated.

The mean progression-free survival (PFS) of the patients who received treatment with pomalidomide and dexamethasone was 15.7 weeks. For those treated with dexamethasone alone the mean time to progression of the disease was 8.0 weeks.

The mean survival time was 12.7 months in patients treated with pomalidomide and dexamethasone. For patients receiving dexamethasone as monotherapy it was 8.1 months.

A total of 31 % of the patients responded to the treatment with pomalidomide and dexamethasone with partial remission, i.e. with a reduction of more than 50 % of the tumour load, compared to 10 % in the dexamethasone group. Also the number of patients with a stable disease was significantly higher in the group treated with pomalidomide than in the comparison group.

INFO: What is dexamethasone?
Dexamethasone, a cortisone medication, is an artificial adrenocortical hormone, a so-called corticosteroid. Dexamethasone has an anti-inflammatory effect and can inhibit the growth of myeloma cells. Pomalidomide is approved in combination with dexamethasone for the treatment of adult patients with recurrent/refractory multiple myeloma who received at least two previous therapies including lenalidomide and bortezomib and presented progression of the diseases during the last therapy. Another corticosteroid which is often used in the treatment of myeloma is prednisone.

Multiple myeloma is still an incurable but well treatable disease, especially when diagnosed early. The pathological cells are never completely eliminated from the body even under a therapy with pomalidomide. However, in order to successfully suppress the disease as long as possible, pomalidomide must be taken on a regular basis and for as long as prescribed by your doctor.

If you experience side effects or you feel the need to discontinue the therapy, discuss this with your attending physician UNDER ANY CIRCUMSTANCES. Only your physician knows what this could mean for the success of your therapy and can offer suitable measures to alleviate the side effects.

The safety and efficacy of pomalidomide was proven in the pivotal studies. Pomalidomide is authorised for the treatment of the relapsed and refractory multiple myeloma in adult patients who received at least two previous therapies, including lenalidomide and bortezomib, and showed progression during the last therapy.

Pomalidomide is currently examined in further clinical studies in combination with other substances. You can find information about current clinical studies regarding multiple myeloma from the organisations mentioned at the end of the brochure.

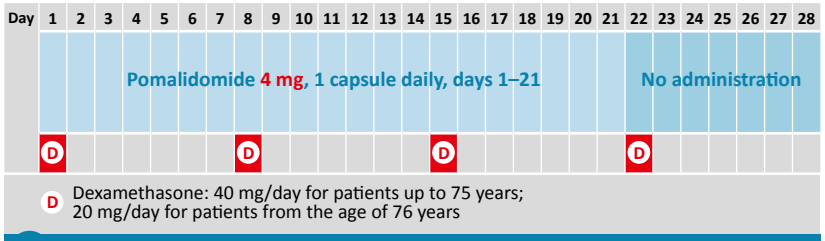
How is pomalidomide administered?

Depending on the treatment plan pomalidomide is taken in the form of hard capsules in different doses by mouth (orally).

The capsules must not be broken or chewed. The drug must not be shared with anyone else even if this person should have the same symptoms as you. Only a physician is authorised to prescribe pomalidomide.

Pomalidomide is taken once a day on days 1 – 21 at repeating 28-day cycles. The recommended standard dose is 4 mg orally once a day.

The recommended dexamethasone dose is 40 mg by mouth once a day on days 1, 8, 15 and 22 of each 28-day cycle. If you are older than 75 years the recommended dexamethasone dose is 20 mg once a day by mouth on the days indicated.



3 Illustration of a cycle with the combination of pomalidomide and dexamethasone

Dose adjustment

Depending on the results of your blood tests, your general health and possible occurrence of side effects, the treatment is adapted, continued or terminated.

If during the treatment of multiple myeloma severe neutropenia develops (lack of white blood cells), i.e. grade 3 to 4, or thrombocytopenia (lack of platelets) or also other severe toxicities (side effects) which are evaluated as pomalidomide-related, an interruption of the treatment and then gradual adjustment with reduced dose is recommended. Your physician will discuss the best possible procedure.

Similarities and differences between pomalidomide and lenalidomide

Just as lenalidomide, pomalidomide belongs to the class of immunomodulatory drugs (IMiDs). Despite the close structural relationship both substances have different effects and side effects.

One of the differences between both substances is that pomalidomide also influences lenalidomide-resistant cancer cells, therefore pomalidomide can also be an effective treatment for patients after failure of lenalidomide treatment.

Pomalidomide is taken by mouth just like lenalidomide and combined with dexamethasone. However, pomalidomide in combination with dexamethasone has a different dose scheme (see figure 3).

In terms of structure, pomalidomide and lenalidomide are both related to thalidomide, an active substance which can cause severe congenital defects. For this reason, a strict contraceptive programme **must** be followed when using pomalidomide.

What side effects are possible?

Pomalidomide was thoroughly examined by the European Medicine Agency before approval. Your physician will carefully weigh the risks against the benefits before deciding on treatment with pomalidomide.

As with all cancer therapies, treatment with pomalidomide can cause certain side effects. These differ from case to case in their nature and extent. **The nursing staff and the physician must be IMMEDIATELY notified about any side effects or changes of your health status under any circumstances.** They can take steps to treat or reduce the side effects.

Important aspects must be taken into consideration when taking pomalidomide. Based on laboratory tests it can be assumed that pomalidomide has a harmful congenital effect, therefore, a contraceptive programme must be STRICTLY followed by women of childbearing age and by men who have sexual contact with women of childbearing age.

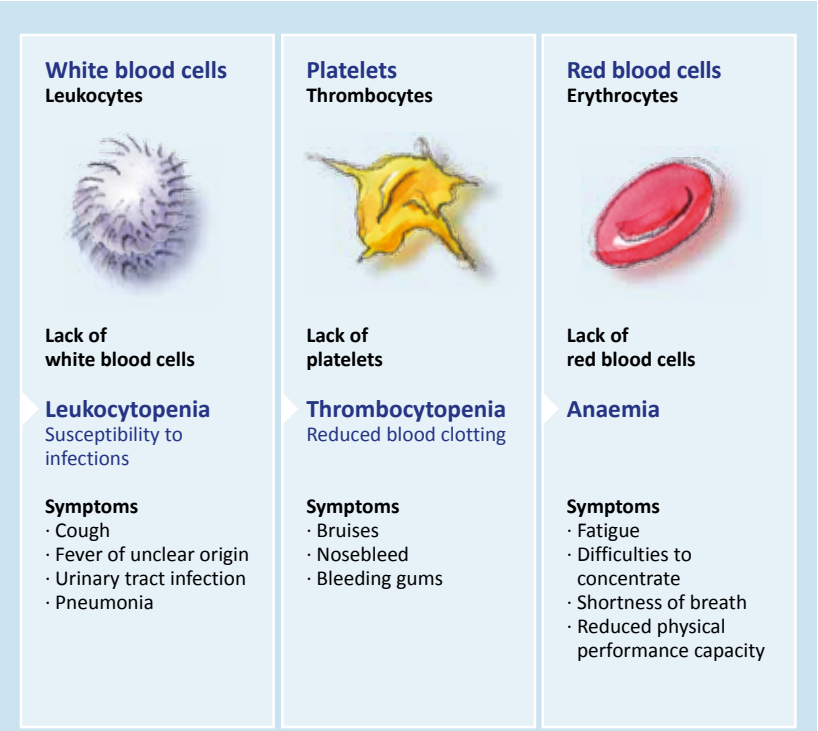
Treatment with pomalidomide can influence the blood formation in the bone marrow. For this reason, **weekly checks of the blood count** are necessary during the first eight weeks of treatment, afterwards monthly tests will suffice.

The **increased risk for the occurrence of blood clots** (thrombosis) **and embolism** must also be taken into consideration which results from the combination of pomalidomide with dexamethasone, erythropoietin or other substances that increase the risk of thrombosis. For this reason, an antithrombotic drug must be administered along with the pomalidomide therapy (e.g. acetylsalicylic acid [ASA] or heparin).

Lack of blood cells

The blood count often temporarily changes when taking pomalidomide. The platelet count can drop (thrombocytopenia) as can the number of white blood cells (leukocytopenia/neutropenia).

In part, also the healthy blood-forming cells are affected by the growth-inhibiting effect of pomalidomide. This means that there may be a lack of white blood cells (leukocytes; defence cells), platelets (thrombocytes; responsible for sealing vessels when bleeding) and, in rare cases, red blood cells (erythrocytes; responsible for oxygen transport).



4 Possible symptoms due to a lack of blood cells

The following problems can develop due to these changes:

- Infections (minor, persistent, but also severe)
- Fever (temperature of over 38.0 degrees Celsius)
- Unusually fast occurrence of haematomas (bruises) and susceptibility for bleeding
- Increasing weakness and fatigue, weakness under normal stress

A lack of blood cells can be detected and treated swiftly by continuously monitoring your blood count. This may be performed in the form of a blood transfusion or by the administration of drugs to support the production of blood cells.

Report signs of an infection (fever, cough, shivering, sore throat, etc.) to your physician **as soon as possible**, since an untreated infection can have a severe course with a reduced white blood cell count. Your physician may prescribe you supportive treatment with blood products or growth factors.

Infection

Patients often develop bacterial diseases or infections such as pneumonia during the treatment with pomalidomide and dexamethasone. These must be treated with anti-infectives **as soon as possible**. You should **immediately** see your attending physician, if you develop any signs of an infection (see above). It is also possible that your physician temporarily prescribes antibiotics to you as a preventive measure in order to reduce the risk of infections.

Blood clots

Another side effect during treatment with pomalidomide is an increased risk of blood clots (venous thrombosis and pulmonary embolism).

By using pomalidomide with dexamethasone blood clotting is intensified and subsequently results in the development of blood clots in the vascular system. If these occur in the arms or legs, these limbs will swell up with pain and redden as a consequence. Your physician will refer to this as thrombosis in the veins of the arms or legs. These symptoms can occur on both sides in rare cases. Parts of these blood clots can get into the lung with the blood flow and clog vessels there. If there are symptoms of a pulmonary embolism, the emergency medical service should be called immediately (Europe-wide emergency number 112).

- It is important to detect the following symptoms:
- Shortness of breath
- Chest pain
- Swelling of the arms or legs

If these symptoms occur your physician will initiate further assessments (ultrasound of the veins or computed tomography of the pulmonary arteries) and, if necessary, administer treatment with anticoagulants (inhibitors of blood clotting) or intensify the previous preventive treatment.

You also can help to prevent thrombosis:

- Avoid sitting still for long periods of time, especially during long flights.
- Do not smoke.
- Wear compression stockings.
- Regular exercise
- Sufficient fluid intake (if possible, at least 2 to 3 litres per day)

The use of drugs for the formation of red blood cells and other drugs which can increase the risk of thrombosis should be carefully and thoroughly considered by multiple myeloma patients who receive combination therapy of pomalidomide and dexamethasone.

Additional adverse drug reactions

Some patients develop **skin rashes** which are usually mild and temporary. Sometimes, however, severe problems can occur and require treatment or in rare cases interruption of the therapy. Please inform your physician, if you notice a skin rash during the treatment with pomalidomide.

Constipation, nausea or **diarrhoea** can also develop. A high-fibre diet helps with constipation (fruit, vegetable, whole grain products). Please inform your physician, if you experience severe diarrhoea (four or more times a day), constipation (no bowel movements for more than three days) or frequent episodes of nausea.

Muscle spasms, chronic fatigue and **swelling of the arms or legs (oedemas)** can also occur during treatment with pomalidomide.

IMMEDIATELY inform your physician, if you develop one of these side effects. Your physician can take the steps necessary to treat or reduce the side effects.

Special care must be taken in patients with **persistent peripheral neuropathy** of grade 2 or higher when receiving treatment with pomalidomide. The symptoms of peripheral neuropathy must be carefully monitored. The damage of peripheral nerve fibres, for example, in the hands, feet, arms and/or legs, causes numbness, tingling, increased sensitivity and pain in the respective regions.

As with all cancer therapies the **occurrence of secondary tumours** is also possible with pomalidomide. The risk must be taken into consideration before starting treatment. In general, the risk of the underlying disease is estimated to be significantly higher than the risk of developing a secondary tumour.

Thorough examinations should be performed before and during treatment with pomalidomide using the usual measures of cancer screening for monitoring and, if necessary, a therapy should be started.

Damage to the embryo (= teratogenicity)

Damage to the embryo, also called embryopathy, is one of the most severe possible side effects of pomalidomide. Animal tests confirmed the teratogenic effect of pomalidomide due to its structure which is related to thalidomide.

The use of pomalidomide is therefore contraindicated during pregnancy and accordingly, contraception is absolutely IMPERATIVE.

Contraception

Special safety measures must be followed during therapy with pomalidomide to prevent that unborn life is exposed to pomalidomide.

Women of childbearing age and men who have sexual contact with women of childbearing age must use effective methods of contraception. **Therefore, please carefully read the following information.**

Rules of contraception for women of childbearing age

Women of childbearing age who receive treatment with pomalidomide must use reliable contraceptive measures for four weeks without interruptions before starting treatment, during treatment and even during interruptions of the treatment as well as up to four weeks after termination of the treatment in order to exclude a pregnancy.

IMPORTANT! Women are considered of childbearing age until they have proof to the contrary. This can only be decided **together** with the attending physician. If in doubt, effective contraceptive methods must always be used. It is important that women of childbearing age are not pregnant at the beginning of the therapy. If you are of childbearing age you will therefore have to undergo regular pregnancy tests before and also during treatment with pomalidomide the results of which are carefully documented.

Your physician will help you find the right birth control, because some contraceptive methods cannot be recommended during treatment with pomalidomide.

The following contraceptive methods are considered **reliable** during the treatment:

- Hormone implant
- Hormone releasing intrauterine device (“coil”, IUD)
- Depot hormone injection (“three-month injection”)
- Closure of the fallopian tubes (tubal ligation)
- Sexual intercourse exclusively with one partner who has had a vasectomy; the vasectomy must be confirmed by two negative semen analyses.
- Certain kinds of the “pill” which only contain the hormone progesterone

The following methods are **not recommended** due to different risks:

- Combined oral (administered by mouth) contraceptives (certain other kinds of the “pill” result in an increased risk of blood clots)
- Copper-releasing intrauterine device (among others, has a higher risk of infections when inserted, menstrual blood loss)
- Condoms – not reliable
- Spermicide (semen-killing cream) – not reliable
- Coitus interruptus (sexual intercourse interrupted before ejaculation) – not reliable
- Rhythm method (“Knaus-Ogino”, counting days) – not reliable

If you would like or have to **change or terminate** the contraceptive method, it is absolutely necessary to have a prior discussion with

- The physician who prescribed the contraception to you
- The physician who prescribed pomalidomide to you

If a patient believes to be pregnant or could be pregnant, she must IMMEDIATELY stop taking pomalidomide and immediately inform her physician. In case of a pregnancy the patient must be referred to a specialist for teratology (the study of congenital disorders).

It is unknown whether pomalidomide is excreted into the breast milk. Therefore, patients must not breastfeed **under any circumstances** if treated with pomalidomide.

Rules of contraception for women of non-childbearing potential

IMPORTANT! Your childbearing potential can only be decided **together** with the attending physician.

Women are considered to be of **non-childbearing potential** if they are older than fifty years and if their period has stopped for at least one year (completed menopause), if they have had a hysterectomy or if they have been sterilised or have any other medically recognised infertility.

Rules of contraception for male patients

Men who receive treatment with pomalidomide must use reliable contraceptive measures during treatment, during interruptions of the therapy as well as up to one week after termination of the treatment in order to exclude pregnancy of their sex partner(s).

Since pomalidomide in men treated with this substance is also present in the seminal fluid, men must use condoms when they have sexual contact with a woman of childbearing age who does not use effective contraceptive methods. This applies during treatment, during interruptions of administration and for one week after termination of the treatment even if you have had a vasectomy in the past.

You must assume that every woman is of childbearing potential until proven to the contrary.

For this reason, men are also **not allowed** to **donate sperm** during treatment, during interruptions of treatment and up to one week after termination of the treatment.

If a patient who takes pomalidomide believes that his sex partner is pregnant or could be pregnant, he must IMMEDIATELY notify his physician.

Important instructions for patients

If you receive therapy with pomalidomide, you must strictly follow all instructions from your physician. He will explain all precautionary measures to you. If something is unclear to you, please ask until you have understood it. Pomalidomide will not be prescribed to you, if you have not understood or consented to the precautionary measures or if it must be assumed that you will not follow them. The amount of drug is sufficient for the first period of therapy. Follow-up prescriptions will ensure a continuous supply.

INFO: The following applies to **Germany:** Pomalidomide is only provided through **T Rezept**, a special type of prescription form. You will only receive your prescription after signing an informed consent form. When issuing each pomalidomide prescription the attending physician will make a special note on the prescription form: “Safety regulations in accordance with summary of product characteristics are met.” As the patient you will only receive pomalidomide at the pharmacy if the prescription includes this note and the date of issue was within the last seven days. If the note is missing, the pharmacy will consult with the physician who issued the prescription.

A special note on the prescription is not necessary in **Austria**.

Ask your attending physician for information about the prescription procedure in **Switzerland**.

Information about storage

- Do not store pomalidomide **above 25 degrees Celsius**. On hot summer days, wrap pomalidomide in aluminium foil, then put it into a cool moist cloth and store in a cool place away from direct sunlight. Alternatively, you can also use a small insulated bag.
- As with other drugs, the following also applies to pomalidomide: The capsules must be **kept out of the reach of children AT ALL TIMES**.
- The capsules must **not** be broken or chewed.
- Pomalidomide is a prescription only drug.
- The drug must not be shared with **anyone else** even if this person should have the same symptoms as you. Only a physician is authorised to prescribe pomalidomide.
- The drug must **not** be given to third parties. Unused capsules must be returned to the pharmacy.

IMPORTANT! If therapy with pomalidomide is indicated for you, your attending physician will provide you with an information brochure which summarises in detail all information about how to handle the drug, its possible side effects and the **necessary** contraceptive measures to be taken. Ask your physician and actively collaborate with him to make your treatment **as effective as possible**.

Questions for your physician

Bring all relevant documents and papers (e.g. medical reports, patient diary, patient ID card, if available) to your next visit and write down all questions which you would like to discuss beforehand. Consider bringing another person to accompany you to your visit, since four ears are better than two.

For each treatment option ask about

- Chances, risks and side effects
- Duration of treatment
- Instructions for use and behaviour in case of intolerance
- Contraindications
- Other treatment options and/or participation in clinical studies
- The option of waiting and observing the situation further before immediately starting treatment
- Accompanying therapy options (e.g. psycho-oncological care)
- Costs which you will have to carry yourself and cost reimbursement

Check whether all of your questions were answered and request a copy of your medical report. Make notes or ask your accompanying person to do so. Always ask if you have not understood something. You have the right to receive explanations to everything in a way you can understand.

Prepare for the discussion with your physician: Write down the questions you would like to ask on a piece of paper and bring this along to your visit.

Some issues you should clarify with your physician during the preliminary discussion about pomalidomide treatment:

- What do you want to achieve with the pomalidomide therapy in my case and is it reasonable at the current stage of my disease?
- If no SHI prescription is issued: Has it been ensured that my health insurance will cover the costs for a therapy with pomalidomide?
- Will I receive pomalidomide in the context of a clinical study?
- What are the goals of the pomalidomide treatment?
- Are there any alternatives to treatment with pomalidomide?
- How much experience do you and your team have with pomalidomide?
- How long will treatment with pomalidomide presumably take?
- Why should I continue taking pomalidomide even if I no longer have any symptoms and feel healthy?
- What side effects can occur?
- Will I receive preventive drugs or aids to prevent or alleviate side effects?
- What will I have to do if certain symptoms develop?
- What side effects must I **immediately** report and to whom?
- What do I have to do if I forget to take the drug?
- What are my options if pomalidomide does not work for me or stops working?
- Have we discussed all possible treatment options, my potential therapy plan and the further procedure?
- Have I received information material about pomalidomide?
- In how far is the pomalidomide therapy similar to the lenalidomide therapy which I received before?
- What is the difference between the pomalidomide therapy and the lenalidomide therapy?
- Where can I get additional information about pomalidomide and multiple myeloma?

If there was not enough time for the discussion, ask for another appointment and a more detailed discussion at a later time, e.g. the next day or at a better time.

You may get more information from a support group or an information or contact point for patients and their families and/or talk to people who already have made experiences with the disease or a certain treatment method.

Consider getting a second opinion and inform your physician about this. Most physicians have no problem with this. Getting a second opinion for extensive treatments is even required by law in some countries and therefore a common procedure these days. Let your physician know whether you were happy with the discussion or not.

Stay realistic and do not let yourself get pressured into a certain treatment.

Take time to make the right decision for you. Obviously, this does not apply to a medical emergency where permanent organ damage may result from lack of treatment. In this case it is important to decide fast.

Refer to pages 33 – 38 to find out where you can get detailed and free information and where you can find a patient organisation or support group in your vicinity.

Additional free information material

Information brochures

Wissenswertes für Patientinnen und Patienten und ihre Angehörigen [Information for patients and their families]

- Bortezomib (Velcade®) – Edition in English
- Lenalidomide (Revlimid) – Edition in English
- Thalidomid (Thalidomide Celgene™)
- Pomalidomide (Imnovid) – Edition in English
- Polyneuropathie
- Multiples Myelom – Von Patient zu Patient
- Therapiebegleiter zum Multiplen Myelom
- Patient Guide for Stem Cell Mobilisation – Edition in English

can be ordered for free from:

LHRM e. V. (Leukämiehilfe RHEIN-MAIN [Leukaemia Support Group Rhine-Main])
Falltorweg 6
D-65428 Rüsselsheim
Phone: +49/(0) 61 42/3 22 40
Fax: +49/(0) 61 42/17 56 42
E-mail: buero@LHRM.de
Internet: www.LHRM.de
www.myelom.net (Myelom-Gruppe LHRM)
www.mds-patienten-ig.org
www.blog4blood.de

About the LHRM e.V.

- The **LHRM e. V.** (Leukämiehilfe RHEIN-MAIN [Leukaemia Support Group]), unlike the name suggests, has committed itself to adult patients with all haematological diseases (which affect the blood and lymph system) and their families since 1991.
- What was started as a group to search for suitable bone marrow donors together with the DKMS (Deutsche Knochenmarkspenderdatei [German Bone Marrow Donor Centre]) in 1991 has developed into a contact and information point as well as patient organisation for patients in Germany and Europe.
- Since then, the **LHRM** has been active in many local, European and international committees and supported the founding of numerous support groups and organisations.
- The **LHRM** is the co-founder of the DLH (Deutsche Leukämie- & Lymphom-Hilfe [German Leukaemia and Lymphoma Support Group]), of the APMM (Arbeitsgemeinschaft Plasmozytom/Multiples Myelom [Working group for Plasmacytoma/Multiple Myeloma]), of the Lymphoma Coalition, of the Myeloma Euronet (since 2012 Myeloma Patients Europe), of the MDS Deutschland, of the H. O. P. E. [Haematological Organisation of Patients in Europe] and of the MDS Patienten Interessen Gemeinschaft [MDS Patient Interest Group].
- The **LHRM** supports the patient environment at hospitals by providing necessary purchases.
- The **LHRM** collaborates in the preparation of patient information brochures.
- The **LHRM** organises patient seminars together with hospitals and practising physicians.
- The **LHRM** offers monthly meetings for patients and their families.

More information on the websites under:
www.LHRM.de
www.myelom.net (Myeloma Support Group LHRM)
www.mds-patienten-ig.org
www.blog4blood.de

How you can help:

If you would like to support our work, we will be happy for any kind of help and ask you to contact us directly.

You could:

- Help us by updating and translating information into English on our website (www.LHRM.de)
- Support us in our public relations work and/or fundraising activities (acquiring donations)
- Finance the layout and/or publication of information material
- Give financial aid to improve the patient environment at hospitals
- Offer a travel stipend to one of our members (or medical personnel) to visit a conference or seminar (many committed patients and families are no longer financially able to cover these costs due to the disease)

Please contact us if you have ideas or questions regarding your support or if you would like to become a member. We look forward to hearing from you!

The **LHRM** is a charitable organisation and a registered association recognised to be especially eligible for funding. Membership fees and donations are tax-deductible. Our registration number is 21 250 75178 (Finanzamt [tax office] Groß-Gerau).

LHRM e. V. (Leukämiehilfe RHEIN-MAIN
[Leukaemia Support Group Rhine-Main])
Falltorweg 6
D-65428 Rüsselsheim
Phone: + 49 / (0) 61 42 / 3 22 40
Fax: + 49 / (0) 61 42 / 17 56 42
E-mail: buero@LHRM.de

Additional contact addresses

Myeloma Patients Europe
www.mpeurope.org

Myeloma Patients Europe (MPE) is an umbrella organisation of myeloma patient groups and associations from all over Europe. MPE was formed following the merger of the European Myeloma Platform and Myeloma Euronet in 2011. The association is registered as a non-profit organisation (AISBL) under Belgian law with its headquarters located in Brussels.

Myeloma UK
www.myeloma.org.uk

Myeloma UK is registered as a charity in 1997. It is the only organisation in the UK focused on myeloma. Its aim is to help myeloma patients to live longer and with a better quality of life by accelerating discovery, development and access to new treatments while helping patients and their families to cope with everything a diagnosis of myeloma brings.

Kompetenznetz Akute und chronische Leukämien
[Competence network for acute and chronic leukaemias]
Dr. Susanne Saussele (Managing Director)
Fakultät für Klinische Medizin Mannheim [Faculty for Clinical Medicine in Mannheim], Universität Heidelberg [University of Heidelberg]
III. Medizinische Universitätsklinik [3rd Medical Department]
Pettenkoferstr. 22
D-68169 Mannheim
Phone: + 49 / (0) 6 21 / 3 83 - 69 66
Fax: + 49 / (0) 6 21 / 3 83 - 69 69
E-mail: zentrale@kompetenznetz-leukaemie.de
Internet: www.kompetenznetz-leukaemie.de

Kompetenznetz Maligne Lymphome e. V.
[Competence network for malignant lymphoma]
Geschäftsstelle
Universitätsklinikum Köln
D-50924 Cologne
Phone: + 49 / (0) 2 21 / 4 78 - 74 00
Fax: + 49 / (0) 2 21 / 4 78 - 74 06
E-mail: lymphome@uk-koeln.de
Internet: www.lymphome.de

BNHO
Berufsverband der Niedergelassenen Hämatologen und Onkologen in Deutschland e. V. [Professional association of practising haematologists and oncologists in Germany]
Geschäftsstelle Köln [Cologne office]
Sachsenring 57
D-50677 Cologne
Phone: + 49 / (0) 2 21 / 9 98 79 80
Fax: + 49 / (0) 2 21 / 99 87 98 22
E-mail: info@bnho.de
Internet: www.bnho.de

DGHO – Deutsche Gesellschaft für Hämatologie und Onkologie e. V.
[German Society of Haematology and Oncology]
ONKOPEDIA
Alexanderplatz 1
D-10178 Berlin
Phone: + 49 / (0) 30 / 27 87 60 89 - 0
Fax: + 49 / (0) 30 / 27 87 60 89 - 18
E-mail: info@dgho.de
Internet: www.dgho-onkopedia.de

DKMS – Deutsche Knochenmarkspenderdatei gemeinnützige Gesellschaft mbH [German Bone Marrow Donor Centre]
Kressbach 1
D-72072 Tübingen
Phone: + 49 / (0) 70 71 / 9 43 - 0
Fax: + 49 / (0) 70 71 / 9 43 - 14 99
Phone: + 49 / (0) 2 21 / 94 05 82 - 40 00
Fax: + 49 / (0) 2 21 / 94 05 82 - 36 99
E-mail: post@dkms.de
Internet: www.dkms.de

Deutsche Krebsgesellschaft e. V. [German Cancer Society]
Kuno-Fischer-Str. 8
D-14057 Berlin
Phone: + 49 / (0) 30 / 3 22 93 29 - 0
Fax: + 49 / (0) 30 / 3 22 93 29 - 66
E-mail: service@krebsgesellschaft.de
Internet: www.krebsgesellschaft.de

Deutsche Krebshilfe e. V. [German Cancer Support Association]
Buschstr. 32
D-53113 Bonn
Phone: + 49 / (0) 2 28 / 7 29 90 - 0
Fax: + 49 / (0) 2 28 / 7 29 90 - 11
E-mail: deutsche@krebshilfe.de
Internet: www.krebshilfe.de

Notes

Haftungsausschluss
Die medizinischen Informationen in dieser Broschüre wurden von ausgewiesenen Fachleuten auf ihre inhaltliche Richtigkeit überprüft. Die Broschüre erhebt keinen Anspruch auf Vollständigkeit und verfolgt nicht den Zweck, den Rat oder die Behandlung durch medizinische Fachkräfte zu ersetzen. Maßgeblich für den Einsatz der Substanz ist ausschließlich die in der aktuellen Fachinformation wiedergegebene Dosierung in der zugelassenen Indikation. Wir fordern alle Leser auf, medizinischen oder psychologischen Rat von ihren jeweiligen Fachkräften einzuholen.

Disclaimer
The medical information in this brochure was checked for accuracy by certified specialists. This brochure is not exhaustive and is not intended to replace the advice or treatment provided by medical specialists. Relevant for the use of the substance is exclusively the dose stated in the current summary of product characteristics and the approved indication. We therefore ask all readers to get medical or psychological advice from their respective specialists.

Leukämiehilfe RHEIN-MAIN e.V.

Thank you for your support!