

**Package leaflet: Information for the patient**

**Pomalidomide Zentiva 1 mg hard capsules  
Pomalidomide Zentiva 2 mg hard capsules  
Pomalidomide Zentiva 3 mg hard capsules  
Pomalidomide Zentiva 4 mg hard capsules**

**Pomalidomide Zentiva is expected to cause severe birth defects and may lead to the death of an unborn baby.**  
• Do not take this medicine if you are pregnant or could become pregnant.  
• You must follow the contraception advice described in this leaflet.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

- What is in this leaflet**
1. What Pomalidomide Zentiva is and what it is used for
  2. What you need to know before you take Pomalidomide Zentiva
  3. How to take Pomalidomide Zentiva
  4. Possible side effects
  5. How to store Pomalidomide Zentiva
  6. Contents of the pack and other information

**1. What Pomalidomide Zentiva is and what it is used for**

**What Pomalidomide Zentiva is**  
Pomalidomide Zentiva contains the active substance 'pomalidomide'. This medicine is related to thalidomide and belongs to a group of medicines which affect the immune system (the body's natural defences).

**What Pomalidomide Zentiva is used for**  
Pomalidomide Zentiva is used to treat adults with a type of cancer called 'multiple myeloma'.  
Pomalidomide Zentiva is either used with:  
• **two other medicines** - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

**Or**  
• **one other medicine** - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

**What is multiple myeloma**  
Multiple myeloma is a type of cancer which affects a certain type of white blood cell (called the 'plasma cell'). These cells grow out of control and accumulate in the bone marrow. This results in damage to the bones and kidneys.

Multiple myeloma generally cannot be cured. However, treatment can reduce the signs and symptoms of the disease, or make them disappear for a period of time. When this happens, it is called 'response'.

**How Pomalidomide Zentiva works**  
Pomalidomide Zentiva works in a number of different ways:

- by stopping the myeloma cells developing
- by stimulating the immune system to attack the cancer cells
- by stopping the formation of blood vessels supplying the cancer cells.

**The benefit of using Pomalidomide Zentiva with bortezomib and dexamethasone**

When Pomalidomide Zentiva is used with bortezomib and dexamethasone, in people who have had at least one other treatment, it can stop multiple myeloma getting worse:

- On average, Pomalidomide Zentiva when used with bortezomib and dexamethasone stopped multiple myeloma from coming back for up to 11 months - compared with 7 months for those patients who only used bortezomib and dexamethasone.

**The benefit of using Pomalidomide Zentiva with dexamethasone**

When Pomalidomide Zentiva is used with dexamethasone, in people who have had at least two other treatments, it can stop multiple myeloma getting worse:

- On average, Pomalidomide Zentiva when used with dexamethasone stopped multiple myeloma from coming back for up to 4 months - compared with 2 months for those patients who used only dexamethasone.

**2. What you need to know before you take Pomalidomide Zentiva**

**Do not take Pomalidomide Zentiva if you:**

- are pregnant or think you may be pregnant or are planning to become pregnant – this is because **Pomalidomide is expected to be harmful to an unborn child.** (Men and women taking this medicine must read the section "Pregnancy, contraception and breast-feeding – information for women and men" below).
- are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see "Pregnancy, contraception and breast-feeding – information for women and men"). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and will provide you with this confirmation.
- are allergic to pomalidomide or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice.

If you are uncertain whether any of the conditions above apply to you, talk to your doctor, pharmacist or nurse before taking Pomalidomide Zentiva.

**Warnings and precautions**  
**Talk to your doctor, pharmacist or nurse before taking Pomalidomide Zentiva if you:**

- have ever had blood clots in the past. During the treatment with Pomalidomide Zentiva you have an increased risk of getting blood clots in your veins and arteries. Your doctor may recommend you take additional treatments (e.g. warfarin) or lower the dose of Pomalidomide Zentiva to reduce the chance that you get blood clots.
- have ever had an allergic reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'.
- have had a heart attack, have heart failure, have difficulty breathing, or if you smoke, have high blood pressure or high cholesterol levels.
- have a high total amount of tumour throughout the body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet).
- have or have ever had hepatitis B infection. Treatment with Pomalidomide Zentiva may cause the hepatitis B virus to become active again in patients who carry the virus, resulting in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- experience or have experienced in the past a combination of any of the following symptoms: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis (TEN) or Stevens-Johnson Syndrome (SJS). See also section 4 "Possible side effects").

It is important to note that patients with multiple myeloma treated with pomalidomide may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed this medicine.

At any time during or after your treatment, tell your doctor or nurse immediately if you: experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with Pomalidomide Zentiva, tell your doctor about any change in these symptoms.

At the end of the treatment you should return all unused capsules to the pharmacist.

**Pregnancy, contraception and breast-feeding – information for women and men**

The following must be followed as stated in the Pomalidomide Zentiva Pregnancy Prevention Programme. Women and men taking Pomalidomide Zentiva must not become pregnant or father a child. This is because pomalidomide is expected to harm the unborn baby. You and your partner should use effective methods of contraception while taking this medicine.

**Women**  
Do not take Pomalidomide Zentiva if you are pregnant, think you may be pregnant or are planning to become pregnant. This is because this medicine is expected to harm the unborn baby. Before starting the treatment, you should tell your doctor if you are able to become pregnant, even if you think this is unlikely.

- If you are able to become pregnant:
- you must use effective methods of contraception for at least 4 weeks before starting treatment, for the whole time you are taking treatment, and until at least 4 weeks after stopping treatment. Talk to your doctor about the best method of contraception for you.
  - each time your doctor writes a prescription for you, he will ensure you understand the necessary measures that have to be taken to prevent pregnancy.
  - your doctor will arrange pregnancy tests before treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished.
- If you become pregnant despite the prevention measures:
- you must stop the treatment immediately and talk to your doctor straight away.

**Breast-feeding**  
It is not known if Pomalidomide Zentiva passes into human breast milk. Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will advise if you should stop or continue breast-feeding.

**Men**  
Pomalidomide Zentiva passes into human semen.

- If your partner is pregnant or able to become pregnant, you must use condoms for the whole time you are taking treatment and for 7 days after the end of treatment.
- If your partner becomes pregnant while you are taking Pomalidomide Zentiva, tell your doctor straight away. Your partner should also tell her doctor straight away.

You should not donate semen or sperm during treatment and for 7 days after the end of treatment.

**Blood donation and blood tests**  
You should not donate blood during treatment and for 7 days after the end of treatment.

Before and during the treatment with Pomalidomide Zentiva you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your doctor should ask you to have a blood test:  
• before treatment  
• every week for the first 8 weeks of treatment  
• at least every month after that for as long as you are taking Pomalidomide Zentiva.

As a result of these tests, your doctor may change your dose of Pomalidomide Zentiva or stop your treatment. The doctor may also change the dose or stop the medicine because of your general health.

**Children and adolescents**  
Pomalidomide Zentiva is not recommended for use in children and adolescents under 18 years.

**Other medicines and Pomalidomide Zentiva**  
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because Pomalidomide Zentiva can affect the way some other medicines work. Also some other medicines can affect the way Pomalidomide Zentiva works.

In particular, tell your doctor, pharmacist or nurse before taking Pomalidomide Zentiva if you are taking any of the following medicines:  
• some antifungals such as ketoconazole  
• some antibiotics (for example ciprofloxacin, enoxacin)  
• certain antidepressants such as fluvoxamine.

**Driving and using machines**  
Some people feel tired, dizzy, faint, confused or less alert when taking Pomalidomide Zentiva. If this happens to you, do not drive or operate tools or machinery.

**Pomalidomide Zentiva contains sodium**  
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

**3. How to take Pomalidomide Zentiva**

Pomalidomide Zentiva must be given to you by a doctor with experience in treating multiple myeloma. Always take your medicines exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

**When to take Pomalidomide Zentiva with other medicines**  
**Pomalidomide Zentiva with bortezomib and dexamethasone**  
• See the leaflets that come with bortezomib and dexamethasone for further information on their use and effects.

- Pomalidomide Zentiva, bortezomib and dexamethasone are taken in 'treatment cycles'. Each cycle lasts 21 days (3 weeks).
- Look at the chart below to see what to take on each day of the 3-week cycle:
  - Each day, look down the chart and find the correct day to see which medicines to take.
  - Some days, you take all 3 medicines, some days just 2 or 1 medicines, and some days none at all.

**PML:** Pomalidomide Zentiva; **BOR:** Bortezomib; **DEX:** Dexamethasone

Cycle 1 to 8				Cycle 9 and onwards			
Medicine name				Medicine name			
Day	PML	BOR	DEX	Day	PML	BOR	DEX
1	√	√	√	1	√	√	√
2	√		√	2	√		√
3	√			3	√		
4	√	√	√	4	√		
5	√		√	5	√		
6	√			6	√		
7	√			7	√		
8	√	√	√	8	√	√	√
9	√		√	9	√		√
10	√			10	√		
11	√	√	√	11	√		
12	√		√	12	√		
13	√			13	√		
14	√			14	√		
15				15			
16				16			
17				17			
18				18			
19				19			
20				20			
21				21			

- After completing each 3-week cycle, start a new one.

**Pomalidomide Zentiva with dexamethasone only**

- See the leaflet that comes with dexamethasone for further information on its use and effects.
- Pomalidomide Zentiva and dexamethasone are taken in 'treatment cycles'. Each cycle lasts 28 days (4 weeks).
- Look at the chart below to see what to take on each day of the 4-week cycle:
  - Each day, look down the chart and find the correct day to see which medicines to take.
  - Some days, you take both medicines, some days just 1 medicine, and some days none at all.

