

# XPOVIO 20MG FILM-COATED TABLETS

Selinexor (20mg)

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## What XPOVIO is used for

XPOVIO is used to treat adult patients with multiple myeloma that has come back after treatment.

XPOVIO is used

- together with two other medicines called bortezomib and dexamethasone in people who had at least one other prior treatment.

OR

together with dexamethasone in patients who have received at least four previous types of myeloma treatment and whose disease cannot be controlled with prior medicines used to treat multiple myeloma.

XPOVIO is also used to treat adult patients with diffuse large B-cell lymphoma (DLBCL) that has come back after at least 2 other prior treatments, who are not suitable for a blood cell transplant.

Multiple myeloma is a cancer which affects a type of blood cell called the plasma cell. A plasma cell normally produces proteins to fight infections. People with multiple myeloma have cancerous plasma cells, also called myeloma cells, which can damage bones and kidneys and increase the risk of infection. Treatment with XPOVIO kills myeloma cells and reduces symptoms of the disease.

Diffuse large B-cell lymphoma (DLBCL) is a type of blood cancer that affects the white blood cell

called lymphocytes. Normal lymphocytes help fight infection in the body, but with DLBCL, healthy lymphocytes change into fast-growing cancer cells that overtake healthy cells and build up in the lymph nodes or other body organs.

## How XPOVIO works

XPOVIO contains the active substance selinexor. Selinexor is a cancer medicine known as an XPO1 inhibitor. It blocks the action of a substance called XPO1 that transports proteins from the cell nucleus into the cell cytoplasm. Some cell proteins must be in the nucleus in order to function properly.

By blocking XPO1 function, selinexor prevents the exit of certain proteins out of the nucleus, and interfering with the continued growth of cancer cells, and leading to the death of cancer cells.

## Before you use XPOVIO

- When you must not use it

### Do not take XPOVIO

If you are allergic to selinexor or any of the other ingredients of this medicine

-Before you start to use it

Before taking XPOVIO, talk to your doctor or pharmacist before taking XPOVIO and during treatment if you:

- have or have had bleeding problems.
- have had a recent infection or get an infection.
- have nausea, vomiting or diarrhoea.
- lose your appetite or lose weight.
- have confusion and dizziness.
- have a decrease in your blood sodium levels (hyponatraemia).
- have a new or worsening cataract.

## Children and adolescents

XPOVIO should not be given to children and adolescents under 18 years.

## Fertility

XPOVIO may impair fertility in females and males.

## Contraception

Women who can become pregnant must use effective contraception during treatment and for at least 1 week after the last dose.

Men are recommended to use effective contraceptive measures or avoid sexual intercourse with women able to have children during treatment and for at least 1 week after the last dose.

## XPOVIO contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 20 mg tablet, that is to say essentially 'sodium-free'.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## How to use XPOVIO

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

## The recommended dose for multiple myeloma is:

- when used together with bortezomib and dexamethasone: 100 mg (5 tablets) once daily, on day 1 of each week, or as directed by your doctor.
- when used with dexamethasone: 80 mg (4 tablets) once daily, on days 1 and 3 of each week, or as directed by your doctor.

## The recommended dose for DLBCL is:

- 60 mg (3 tablets) once daily, on days 1 and 3 of each week until

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disease progression or unacceptable toxicity, or as directed by your doctor.

Your doctor may alter your dose if side effects occur.

It is important to take this medicine exactly as your doctor has told you to avoid dosing errors.

## Method of use

Swallow XPOVIO tablets whole with a glassful of water, either with food or between meals. Do not chew, crush, divide or break the tablets in order to prevent risk of skin irritation from the active substance.

## - When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

## - How long to use it

Your doctor will let you know the duration of treatment based on how you are responding to treatment and side effects.

Do not stop taking or change your dose of XPOVIO without your doctor's approval. However, if you become pregnant while taking XPOVIO, you must immediately stop treatment and inform your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## - If you forget to use it

Do not take a double dose to make up for a forgotten dose. Also, do not take an extra dose if you vomit after taking XPOVIO. Take your next dose when scheduled.

- If you use too much (overdose) Call your doctor or go to the nearest hospital emergency room right away. Take your box of XPOVIO tablets with you.

## While you are using XPOVIO

### - Things you must do

Tell your healthcare provider right away if you have any bleeding or easy bruising during treatment with XPOVIO.

### - Things you must not do

#### Driving and using machines

XPOVIO can cause fatigue, confusion and dizziness. Do not drive or use machines if you get such a reaction while being treated with this medicine.

#### Pregnancy

A pregnancy test is recommended before XPOVIO treatment for women able to have children.

Do not use XPOVIO during pregnancy as it can harm the unborn child. Women who become pregnant while taking XPOVIO must immediately stop treatment and inform the doctor.

#### Breast-feeding

Do not breast-feed during treatment with XPOVIO or 1 week after the last dose, as it is unknown whether selinexor or its metabolites are excreted in human milk and cause harm to the breast-fed children.

### - Things to be careful of

Your doctor will examine you and you will be monitored closely during treatment. Before starting XPOVIO and during treatment, you will have blood tests to check that you have enough blood cells.

#### Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the following side effects.

XPOVIO may cause the following **serious side effects**:

## Very common (may affect more than 1 in 10 people)

### • **reduced number of blood platelets**

Your doctor will carry out blood tests before you start taking XPOVIO, and as needed during and after treatment. These tests will be more frequent during the first two months of treatment to monitor your blood platelet counts. Your doctor may stop treatment or adjust the dose based on your platelet counts. Tell your doctor immediately if you have signs of reduced number of blood platelets such as:

- easy or excessive bruising
- skin changes that appear as a rash of pinpoint-sized reddish-purple spots
- prolonged bleeding from cuts
- bleeding from your gums or nose
- blood in your urine or stools

### • **reduced number of red and white blood cells**, including neutrophils and lymphocytes.

Your doctor will carry out blood tests to monitor your red and white blood cell counts before you start taking XPOVIO and as needed during and after treatment. These tests will be more frequent during the first two months of treatment. Your doctor may stop treatment or adjust the dose based on your blood cell counts or may treat you with other medicines to increase cell counts. Tell your doctor immediately if you have signs of reduced neutrophils such as a fever.

### • **fatigue**

Inform your doctor if you experience new or worsening fatigue. Your doctor may adjust the dose in case of persistent or worsening fatigue.

### • **nausea, vomiting, diarrhoea**

Inform your doctor immediately if you develop nausea, vomiting or diarrhoea. Your doctor may adjust the dose or stop treatment based on the severity of your symptoms. In addition, your doctor may prescribe you medicines to take before or during XPOVIO treatment to prevent

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and treat nausea and/or vomiting and/or diarrhoea.

- **decreased appetite and/or weight**

Your doctor will weigh you before you start taking XPOVIO and as needed during and after treatment. This will be more frequent during the first two months of treatment. Tell your doctor if you lose your appetite and if you lose weight. Your doctor may adjust the dose in case of reduced appetite and weight and/or prescribe medicines to increase your appetite. Maintain adequate fluid and caloric intake throughout your treatment.

- **reduced sodium level**

Your doctor will carry out blood tests to check your sodium level before you start taking XPOVIO, and as necessary during and after treatment. These tests will be more frequent during the first two months of treatment. Your doctor may adjust the dose and/or prescribe salt tablets or fluids based on your sodium level.

- **confusional state and dizziness**

Inform your doctor if you experience confusion. Avoid situations where dizziness or confusional state may be a problem and do not take other medications that may cause dizziness or confusional state without talking to your doctor. Do not drive or operate machines if you experience any confusion or dizziness until it resolves. Your doctor may adjust the dose to reduce these symptoms.

- **cataract**

Inform your doctor if you experience symptoms of cataract such as double vision, sensitivity to light or glare. If you notice changes with your vision, your doctor may request an eye examination by an eye specialist (an ophthalmologist) and you may need eye surgery to remove the cataract and restore your vision.

Tell your doctor or nurse immediately if you notice any of the other following side effects as listed below.

**Other possible side effects are:**

**Very common** (may affect more than 1 in 10 people):

- Upper respiratory tract infection
- Pneumonia
- Bronchitis
- Viral infection of the nose and throat (Nasopharyngitis)
- Damage to nerves in the hands and feet that can cause tingling and numbness
- Bleeding from nose
- Headache
- Dehydration
- Increased blood sugar level
- Loss of sleep
- Impaired sense of taste
- Blurred vision
- Shortness of breath
- Cough
- Abdominal pain
- Constipation
- Loss of energy
- Fever
- Nausea
- Vomiting
- Diarrhoea
- Tender and painful joints
- Hypophosphataemia
- Hypomagnesaemia
- Hyperamylasaemia
- Hyperlipasaemia

**Common** (may affect more than 1 in 100 people)

- Mental confusion
- Confusing thinking
- Fainting
- Increase in heart rate
- Low vision
- Loss of taste
- Loss of balance
- Disturbance in attention
- Memory impairment
- Low blood pressure
- Spinning sensation
- Indigestion, dry mouth, abdominal discomfort

- Flatulence or bloating
- Skin itchiness
- Muscle spasm
- Loss of hair
- Night sweats including excessive sweating
- Lower respiratory tract infection
- Bruise
- Sepsis
- Dehydration
- Loss of sleep
- Nose bleeding
- Shortness of breath
- Nausea
- Vomiting
- Diarrhoea
- Hypercreatinemia
- Decreased urine amount
- Swelling in legs, ankle or feet
- General physical health deterioration
- Malaise
- Dark colored urine or light-colored stool
- Jaundice
- Fall

**Uncommon** (may affect up to 1 in 100 people):

- rapid break down of tumour cells that could be potentially life-threatening and cause the symptoms as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath (tumour lysis syndrome)
- inflammation of brain that could cause confusion, headache, seizures (encephalopathy)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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## Storage and Disposal of XPOVIO

### - Storage

Store XPOVIO at or below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister pack, the inner carton, and the outer carton after "EXP." The expiry date refers to the last day of that month.

### - Disposal

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

## Product Description

### - What it looks like

XPOVIO film-coated tablets are blue, round, with "K20" debossed on one side.

Each outer carton contains four blisters. Each blister contains 4, 5, 6 or 8 tablets, providing a total of 16, 20, 24 or 32 tablets.

### - Ingredients

#### - Active ingredients (s)

The active substance is selinexor. Each film-coated tablet contains 20mg selinexor.

#### - Inactive ingredients

The other ingredients are microcrystalline cellulose, croscarmellose sodium, povidone K30, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate. For the tablet coating the ingredients are talc, poly(vinyl alcohol) partially hydrolysed, glyceryl monostearate, polysorbate 80, titanium dioxide, macrogol, indigo carmine aluminium lake and brilliant blue FCF aluminium lake.

### - MAL number:

MAL24086004ACRZ

## Manufacturer

Catalent CTS, LLC  
10245 Hickman Mills Drive  
Kansas City, Missouri 64137 USA.

## Product Registration Holder

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm  
No. 1 Jalan SS 7/26A, Kelana Jaya  
47301 Petaling Jaya,  
Selangor Darul Ehsan, Malaysia.

## Date of revision

25/08/2025

## Serial Number

NPRA (R1) 24/01

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