

ELIPIX FILM COATED TABLETS

Etoricoxib 60mg, 90mg, 120mg

What is in this leaflet

1. What Elipix tablet is used for
2. How Elipix tablet works
3. Before you use Elipix tablet
4. How to use Elipix tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Elipix tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Elipix tablet is used for

Your doctor has prescribed Elipix tablet for:

- treatment of osteoarthritis
- treatment of rheumatoid arthritis
- treatment of ankylosing spondylitis
- treatment of acute pain after minor dental procedures
- treatment of menstrual pain
- treatment of gout

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that cushions the ends of the bones, resulting in pain, inflammation, tenderness, stiffness, and physical disability.

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of functions in the joints and inflammation in other body organs.

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

Gout is a disorder characterized by sudden, recurring attacks of pain and inflammation in one or more joints.

You may obtain further information from your doctor or pharmacist, who have more detailed information.

How Elipix tablet works

Elipix tablet is a member of a group of medicines called selective COX-2 inhibitors that are used to reduce pain and inflammation. Elipix tablet is not a narcotic.

Before you use Elipix tablet

- When you must not use it

Do not take Elipix tablet if you:

- are allergic to etoricoxib or any of other ingredients of this medicine.
- have had heart failure, a heart attack, bypass surgery, chest pain, narrow or blocked arteries of the extremities, a stroke or mini stroke
- have high blood pressure that has not been controlled by treatment
- are or could be pregnant

- Before you start to use it

Tell your doctor about any medical problems or allergies you have or have had, including:

- history of angina, heart attack or a blocked artery in your heart
- narrow or blocked arteries of the extremities
- kidney disease
- liver diseases
- dehydration, for example by a prolonged bout of vomiting or diarrhea
- have or had ulceration, bleeding or perforation of your stomach or intestines
- heart failure
- high blood pressure
- swelling due to fluid retention
- an allergic reaction to aspirin or other anti-inflammatory medicines (commonly known as NSAIDs)
- a history of stroke or mini stroke
- conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.
- being treated for an infection. Elipix tablet can mask or hide a fever, which is a sign of infection.
- have had asthma, nasal inflammation, and/or itching or hives caused by Aspirin or NSAIDs.
- suffering from dyspepsia (indigestion).

Etoricoxib may cause severe skin reactions. Symptoms may include skin rash, blisters and peeling of the skin. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance

right away.

Use in elderly

Elipix tablet works equally well in older and younger adult patients. Adverse experiences may occur at a higher incidence in older patients compared to younger patients. If you are elderly (i.e., over 65 years of age), your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for older patients.

Use in pregnancy and breastfeeding

Tell your doctor if you are:

- Elipix tablet may cause fetal harm and should not be used by a woman who is attempting to become pregnant or becomes pregnant during treatment.
- Breastfeeding or plan to breastfeed.

- Taking other medicines

You should always tell your doctor about all medicines that you are taking to plan to take, including those obtained without a prescription.

Your doctor may want to check that your medicines are working properly if you are taking:

- warfarin (a blood thinner)
- rifampin (an antibiotic)
- diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers (medicines used for high blood pressure and heart failure)
- lithium (a medicine used to treat a certain type of depression)
- birth control pills
- hormone replacement therapy
- methotrexate (a medicine used for suppressing the immune system)

Elipix tablet can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because Elipix tablet cannot substitute for aspirin for this purpose.

How to use Elipix tablet

- How much to use

Elipix tablet should be taken once a day. You may take Elipix tablet with

ELIPIX FILM COATED TABLETS

Etoricoxib 60mg, 90mg, 120mg

or without food.

Your doctor will decide what dose of Elipix tablet you should take and how long you should take.

For treatment of rheumatoid arthritis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed

For treatment of ankylosing spondylitis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Acute pain conditions:

- The recommended dose is 90mg or 120mg once daily. Elipix should be used only for the acute period limited to a maximum of 8 days.

For the relief of gout attacks and the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after minor dental procedures

- The recommended dose is 90 mg once a day.

Do not exceed the daily doses for each condition stated above.

If you have mild or moderate liver disease, your doctor might prescribe you a lower dose or recommend that you do not take Elipix.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Elipix tablet as recommended by doctor or pharmacist.

- If you forget to use it

Try to take Elipix tablet as prescribed. However, if you miss a dose, please do not take an extra dose. Just resume your usual schedule the following day.

- If you use too much (overdose)

If you take more than the prescribed dosage, contact your doctor immediately.

While you are using it

- Things you must do

Consult your doctor if:

- Any of the following symptoms appear or worsen: shortness of breath, chest pains or ankle swelling. Stop your treatment with Elipix tablet and consult a doctor, as soon as is practical.
- You have kidney, liver or heart disease, your doctor will want to appropriately keep a check on you.
- You develop any symptoms that could indicate a severe allergic reaction such as inability to breathe or a serious skin reaction, you must consult a doctor on an urgent basis.

Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that control your pain.

Elipix tablet can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, in order to ensure that it is safe to continue the treatment.

- Things you must not do

Do not share Elipix tablet with anyone else; it was prescribed only for you.

Do not take Elipix tablet for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

- Things to be careful of

Be careful driving or operating machinery until you know how Elipix affects you.

Elipix contains lactose. If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking this medicinal product.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. Like all prescription medicines, Elipix tablet may cause side effects.

Some of the side effects are:-

- dizziness,
- swelling of the legs and/or feet,
- weakness and fatigue,
- high blood pressure,
- nausea,
- heartburn,
- upset stomach,
- headache,

Additionally, the following have been reported:

- allergic reactions (which may be serious enough to require immediate medical attention) including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, wheezing, rash, itching and hives;
- redness of the skin,
- severe skin reactions which may occur without warning,
- taste alteration,
- abnormal rhythm of the heart,
- heart failure,
- palpitations,
- feeling of tightness, pressure or heaviness in the chest,
- stomach pain,
- stomach ulcers that may become serious and may bleed and may occur at any time during use and without warning,
- vomiting,
- liver problem including liver failure, yellowing of the skin and eyes (jaundice)
- serious kidney problems
- high levels of potassium in your blood,
- insomnia
- anxiety
- depression
- restlessness
- drowsiness
- mouth ulcers
- diarrhea,
- severe increase in blood pressure,
- confusion,
- hallucinations,
- platelets decreased, blurred vision

Other side effects may also occur rarely, and as with any prescription medicine, some side effects may be serious. Ask your doctors or pharmacist for more information.

ELIPIX FILM COATED TABLETS

Etoricoxib 60mg, 90mg, 120mg

Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

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

Storage and Disposal

- Storage

Store below 30°C.

Keep Elipix tablet and all medicines safely away from children.

Do not use this medicine after the month and year shown by the numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

- Disposal

Medicines should not be disposed of via wastewater or household water. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

- Elipix 60mg: Blue-green, round shaped film-coated tablet debossed with 'N' on one side and '15' on the other side.
- Elipix 90mg: White, round shaped film-coated tablet debossed with 'N' on one side and '14' on the other side.
- Elipix 120mg: Pale green, round shaped film-coated tablet debossed with 'N' on one side and '13' on the other side.

- Ingredients

- Active Ingredients:
Etoricoxib

- Inactive ingredients:
Core tablet

- Anhydrous Dibasic Calcium Phosphate
- Microcrystalline Cellulose

- Croscarmellose Sodium
- Magnesium Stearate

Film coating

- Elipix 60mg: Opadry II Complete Film Coating System 32K510049 Green
- Elipix 90mg: Opadry II Complete Film Coating System 32K580000 White
- Elipix 120mg: Opadry II Complete Film Coating System 32K510012 Green

- MAL number

MALXXXXXXXXXX

Manufacturer

Novugen Pharma Sdn. Bhd.
No. 27, Jalan Lengkok Teknologi 2,
Taman Teknologi Enstek Fasa 1,
71760, Bandar Baru Enstek,
Negeri Sembilan, Malaysia.

Product Registration Holder

Novugen Pharma Sdn. Bhd.
No. 3, Jalan Jururancang U1/21,
Hicom Glenmarie Industrial Park,
40150 Shah Alam,
Selangor, Malaysia.

Date of Revision

19/10/2022

Serial Number

NPRA(R2) 22/085