

**Orotix**  
(etoricoxib)  
60mg, 90mg, 120mg  
Film-Coated Tablets

**Mode of action**

'Orotix' is a non-steroidal anti-inflammatory drug (NSAID). It is a member of a class of NSAIDs known as cyclo-oxygenase-2 (COX-2) selective inhibitors. Cyclo-oxygenase is an enzyme responsible for the generation of prostaglandins, which are naturally occurring chemicals in the body that can cause pain and inflammation. The production of prostaglandins by the enzyme COX-2 is increased in certain diseases such as arthritis. By blocking COX-2, 'Orotix' reduces the amount of prostaglandins produced and reduces pain and inflammation.

**Contraindications**

Do not take 'Orotix' if any of the following applies to you:

- You are allergic to any of the ingredients
- You have an active stomach ulcer or bleeding in the stomach or intestines
- You have serious liver disease
- You have serious kidney disease
- You have previously experienced any of the following after taking aspirin (acetylsalicylic acid) or other anti-inflammatory medications (NSAIDs including COX-2 inhibitors): asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps, or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash
- You are or could be pregnant or are breast-feeding.
- You are under 16 years of age
- You have inflammatory bowel disease
- You have been diagnosed with heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, any kind of stroke (including a "mini-stroke" or a transient ischaemic attack or "TIA").

'Orotix' may slightly increase your risk of heart attack and stroke and this is why it should not be used by people who have already had heart problems or stroke.

- You have high blood pressure that has not been controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is under control).

## **Precautions**

If you answer 'yes' to any of the following questions and you have not already discussed these with your doctor, go back to your doctor and ask for advice. 'Orotix' may not be suitable for you, or you may need to be regularly monitored while taking it:

- Do you have a history of stomach bleeding or ulcers?
- Are you dehydrated, for example by a prolonged bout of vomiting or diarrhea?
- Do you have a tendency to swelling due to fluid retention?
- Do you have or have previously had liver or kidney disease?
- Are you being treated for an infection? 'Orotix' can mask or hide a fever which is a sign of infection
- Are you a woman trying to become pregnant?
- Do you have any conditions such as high blood pressure, diabetes, and high cholesterol or are you are a smoker? These can increase your risk of heart disease and you need to discuss with your doctor if this medicine is suitable for you.

## **Use in pregnancy and breast feeding**

'Orotix' tablets should not be taken during pregnancy. If you are pregnant or think you could be pregnant, or if you are planning to become pregnant, do not take the tablets. If you become pregnant, stop taking the tablets and consult your doctor if you are unsure or need more advice.

It is not known if 'Orotix' is excreted in human milk. If you are taking 'Orotix' you should not breast-feed. Consult your doctor before taking 'Orotix' if you are breast-feeding, or planning to breast-feed.

## **Use in children**

'Orotix' tablets should not be used in children or adolescents under 16 years of age.

## **Use in elderly patients**

'Orotix' works equally well in and is equally well-tolerated by older and younger adult patients. No dosage adjustment is necessary for elderly patients.

## **Drug interactions**

'Orotix' may interfere with a few other medicines so it is important that you always tell your doctor about any other medications you are taking, including those obtained without a prescription.

In particular if you are taking any of the following medicines, your doctor may want to monitor you to check that your medicines are working properly, once you start taking 'Orotix':

- ACE inhibitors and angiotensin receptor blockers (medicines for high blood pressure and heart failure)
- Anti-clotting agents such as warfarin or other oral anticoagulants which are used to thin the blood and prevent blood clots
- Birth control pills
- Ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- Digoxin (a medicine for heart failure and irregular heart rhythm)
- Diuretics (water tablets)
- Hormone replacement therapy (HRT)
- Lithium (a medicine used to treat some types of depression)
- Methotrexate (a drug often used in rheumatoid arthritis for suppressing the immune system)
- Minoxidil (a drug used to treat high blood pressure)
- Salbutamol in tablet or oral solution form by mouth (a medicine for asthma)
- Rifampicin (an antibiotic)

'Orotix' can be taken with low dose aspirin. If you are currently taking low dose aspirin for the prevention of heart attack or stroke, you should not stop this without consulting your doctor because 'Orotix' cannot substitute for aspirin for this purpose. You should be aware that the risk of stomach ulcers is greater if you are taking aspirin with 'Orotix' and you should not take higher doses of aspirin, or any other anti-inflammatory medications while taking 'Orotix'.

### **Driving and operating machinery**

Dizziness and sleepiness have been reported in some patients taking 'Orotix'. If you experience dizziness or sleepiness, you should refrain from driving or operating machinery.

### **Dosage and administration**

Take 'Orotix' tablets by mouth once a day. 'Orotix' can be taken with or without food, although the onset of drug effect may be faster if taken without food, when rapid relief of symptoms is required.

Don not exceed the recommended dose for the treatment of your condition.

**Osteoarthritis:** The recommend dose is 60mg once a day.

**Rheumatoid arthritis:** The recommend dose is 90mg once a day.

**Gout:** The recommended dose is 120mg once a day which should only be used for the acute painful period and for a maximum of 8 days.

The doses recommended above for each condition should NOT be exceeded. Doses higher than these have been shown not to provide any additional benefit.

**Important dose information for patients with liver disease:** If you have mild liver disease, you should NOT take more than 60mg a day regardless of what disease you are taking 'Orotix' for. If you have moderate liver disease, you should NOT take more than 60mg 'Orotix' **every other day**.

Your doctor will have decided which dose is appropriate for you and it is important that you take your tablets as your doctor has instructed.

**What should you do if you miss a dose or take too much 'Orotix'?**

It is important to keep to the dose the doctor has prescribed. If you miss a dose, leave out that dose completely, do not take an extra dose to make up and just resume your usual schedule the following day.

You should never take more tablets than the doctor recommends. If you do take too many 'Orotix' tablets, you should seek medical attention immediately. Make sure you take the original container of the tablets with you.

**Side effects**

Like all medicines 'Orotix' can have unintended or undesirable effects, so – called side effects, in some patients. In studies and in general use, the side effects that occurred in patients treated with 'Orotix' were as follows:

**Common (may affect 1 or more persons in 100 but less than 1 in 10)**

Weakness and fatigue; dizziness; flu-like illness; diarrhea; indigestion (dyspepsia); stomach pain or discomfort; heartburn; nausea; changes in blood tests related to the liver; headache; swelling of the legs and/or feet due to fluid retention (oedema); raised blood pressure.

**Uncommon (may affect less than 1 person in 100)**

Abdominal bloating; chest pain; swelling of the face; flushing; upper respiratory infection; decreases in blood cell counts; heart failure; bruising; bowel movement pattern change; constipation; dry mouth; taste alteration; gastroenteritis; wind; stomach ulcer; irritable bowel syndrome; mouth ulcers; vomiting; blurred vision; nose bleed; ringing in the ears; appetite change; weight gain; muscle cramp/spasm; muscle pain/stiffness; inability to sleep; numbness or tingling; sleepiness; anxiety; depression; decrease in mental acuity; breathlessness; cough; skin rash or itchy skin; urinary tract infection.

**Very rare (may affect less than 1 person in 10,000)**

Allergic reactions (which may be serious enough to require immediate medical attention) including hives, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing; heart attack; inflammation of the stomach lining or stomach ulcers that may become serious and may bleed; stroke; serious kidney problems.

Consult your doctor or seek medical advice, if you experience any of the above side-effect or any other unusual symptoms you do not understand and particularly if they are persistent, troublesome or getting worse.

It will be helpful if you make a note of what you experienced, when it started and how long it lasted.

**Storage conditions**

Store below 30°C.