

Obetinext

(As per Innovator's Specifications)

Obeticholic Acid 5mg, 10mg (Manufacturer's Specifications)

COMPOSITION

Obetinext 5mg Tablet: Each film coated tablet contains: Obeticholic Acid 5mg

(As per Innovator's Specifications)

Obetinext 10mg Tablet: Each film coated tablet contains: Obeticholic Acid 10mg

(As per Innovator's Specifications)

What Obetinext is and what it is used for

Obetinext contains the active substance obeticholic acid (farnesoid X-receptor agonist) which helps to improve how your liver works by reducing the production and build up of bile in the liver and also reducing inflammation.

This medicine is used to treat adult patients with a type of liver disease known as primary biliary cholangitis, either by itself or together with another medicine, ursodeoxycholic acid.

What you need to know before you take Obetinext

Do not take Obetinext

- If you are allergic to obeticholic acid or any of the other ingredients of this medicine (listed in section 6).
- If you have primary biliary cholangitis with liver cirrhosis with symptoms such as fluid in the belly or confusion (decompensated liver cirrhosis).
- If you have a complete blockage of the biliary tract (liver, gallbladder and bile ducts).

Warnings and precautions

Talk to your doctor or pharmacist before taking Obetinext.

Your doctor may need to interrupt or discontinue Obetinext if your liver function gets worse. Your doctor will do blood tests to monitor the health of your liver when you start treatment and regularly from there on.

Itching may occur when taking Obetinext and may sometimes become severe (intense itching or itching over much of your body). Your doctor may prescribe other medicines for treatment of itching or adjust your dose of Obetinext. If you experience itching that is difficult to tolerate, talk to your doctor.

Children and adolescents

This medicine is not for use in children or adolescents.

Other medicines and Obetinext

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

In particular, tell your doctor if you are taking so-called bile acid binding resins (cholestyramine, colestipol, colesvelam) used to lower blood cholesterol levels as they may lessen the effect of Obetinext. If you take any of these medicines, take Obetinext at least 4 to 6 hours before or 4 to 6 hours after taking bile acid binding resin, giving as much time as possible.

The levels of some medicines such as theophylline (a medicine to help breathing) or tizanidine (a medicine to relieve the stiffness and restriction of muscles) may be increased and need to be monitored by your doctor while taking Obetinext. Your doctor may need to monitor how well your blood clots when taking medicines such as warfarin (a medicine to help your blood flow) with Obetinext.

Pregnancy

There is no experience using Obetinext in pregnancy. As a precautionary measure, you should not take Obetinext if you are pregnant.

Breast-feeding

It is not known if this medicine passes into human milk. Your doctor will determine whether you should discontinue breast-feeding or discontinue/abstain from Obetinext therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for you.

Driving and using machines

This medicine has no or negligible influence on your ability to drive or use machines.

Obetinext contains sodium

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

How to take Obetinext

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

Prior to initiation of treatment with Obetinext, your hepatic status must be known. If you have primary biliary cholangitis with liver cirrhosis with symptoms such as fluid in the belly or confusion (decompensated liver cirrhosis) or if you have a complete blockage of the biliary tract (liver, gallbladder and bile ducts) this should be determined (see section 2. Do not take Obetinext, Warnings and precautions).

The recommended starting dose is one 5 mg film-coated tablet once daily.

Your doctor may adjust your dose depending on your liver function or if you experience itching that is difficult to tolerate.

Depending on your body's response after 6 months, your doctor may increase your dose to 10 mg once daily. Your doctor will discuss any change of dose with you.

You can take Obetinext with or without food. If you take bile acid binding resins, take this medicine at least 4 to 6 hours before or at least 4 to 6 hours after the bile acid binding resins (see section "Other medicines and Obetinext").

If you take more Obetinext than you should

If you accidentally take too many tablets, you may experience itching or liver-related side effects such as yellowing of the skin. Contact a doctor or go to a hospital for advice immediately.

If you forget to take Obetinext

Skip the missed dose and take your next dose when you would normally take it. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Obetinext

You should continue to take Obetinext for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

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

Tell your doctor or pharmacist if you experience itching of the skin (pruritus) or if the itch gets worse while on this medicine. In general itching of the skin is a very common (may affect more than 1 in 10 people) side effect that begins within the first month following the start of treatment with Obetinext and usually becomes less severe over time.

Other possible side effects may be:

Very common side effects

- stomach pain
- feeling tired

Common side effects (may affect up to 1 in 10 people)

- thyroid hormone irregularity
- dizziness
- fast or irregular heart beat (palpitations)
- pain in the mouth and throat
- constipation
- itchy, dry and/or red skin (eczema)
- rash
- pain in your joints
- swelling in the hands and feet
- fever

Not known (frequency cannot be estimated from the available data)

The following side effects have been reported since the marketing of Obetinext, but how often they occur is not known:

- liver failure
- increase in bilirubin (liver blood test)
- yellowing of eyes or skin (jaundice)
- scarring of the liver (cirrhosis)

STORAGE

Store below 30°C. Protect from light and moisture.

HOW SUPPLIED

Obetinext 5mg Tablets: Pack of 20's, 30's film coated tablets.

Obetinext 10mg Tablets: Pack of 20's, 30's film coated tablets.

TO BE SOLD ON THE PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

PLEASE READ THE CONTENTS CAREFULLY BEFORE USE. THIS PACKAGE INSERT IS CONTINUALLY UPDATED FROM TIME TO TIME

Lactose & Gluten Free

اوبینیٹیکسٹ

(او بیٹیکولک ایسڈ)

5 ملی گرام

10 ملی گرام

قلم کوڈ گولیاں

خوراک و دایات:

ڈاکٹر کی دایات کے مطابق استعمال کریں۔

صرف صفو ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام اڈویٹ پیچ کی تیج سے دور رکھیں۔

دوا کو 30°C سے کم درجہ حرارت پر رکھیں اور روشنی سے محفوظ رکھیں۔

NEXT
PHARMACEUTICAL

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