

Package Leaflet: Information for The User

# ETOSPEED®-MR

[Etoricoxib & Thiocolchicoside Tablets]

This product is available as the above name but will be referred to as ETOSPEED®-MR throughout 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.

## What is in this leaflet

1. What ETOSPEED®-MR is and what it is used for
2. What you need to know before you take ETOSPEED®-MR
3. How to take ETOSPEED®-MR
4. Possible side effects
5. How to store ETOSPEED®-MR
6. Contents of the pack and other information

### 1. What ETOSPEED®-MR is and what it is used for

ETOSPEED®-MR is combination of active substance etoricoxib and thiocolchicoside (muscle relaxant).

Etoricoxib is a medication belonging to the class of nonsteroidal anti-inflammatory drugs (NSAIDs). It's primarily used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis, acute gouty arthritis, and other musculoskeletal disorders. Etoricoxib works by inhibiting the enzyme cyclooxygenase-2 (COX-2), which is involved in the production of prostaglandins that cause pain and inflammation.

Thiocolchicoside is primarily used as a skeletal muscle relaxant to alleviate muscle spasms and stiffness associated with various musculoskeletal conditions. Thiocolchicoside is commonly prescribed for the relief of acute and chronic muscle spasms. It helps relax muscles by acting on the central nervous system, specifically by enhancing the activity of gamma-aminobutyric acid (GABA) receptors in the spinal cord. It is used in conditions such as: Low Back Pain- Often prescribed for acute or chronic lower back pain associated with muscle spasms. Cervical Spondylosis: Helps alleviate muscle stiffness and spasms in the neck region due to cervical degenerative changes. Post-Traumatic and Post-Surgical Conditions: Thiocolchicoside may be used to manage muscle spasms and stiffness following trauma or surgery.

ETOSPEED®-MR is commonly used for the acute treatment of musculoskeletal disorders associated with painful muscle spasm in adults.

## **2. What you need to know before you take ETOSPEED®-MR**

### **Do not take ETOSPEED®-MR:**

- If you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of this medicine
- If you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors.
- If you have a current stomach ulcer or bleeding in your stomach or intestines
- If you have serious liver disease
- If you have serious kidney disease
- If you are or could be pregnant or are breast-feeding
- If you are under 16 years of age
- If you have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis
- If 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 adequately controlled)
- If your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain)
- If you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries).
- If you have had any kind of stroke (including mini-stroke, transient ischaemic attack).

Etoricoxib may slightly increase your risk of heart attack and stroke and this is why it should not be used in those who have already had heart problems or stroke.

If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking ETOSPEED®-MR if:

- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- You have swelling due to fluid retention.
- You have a history of heart failure, or any other form of heart disease.
- You have a history of high blood pressure. ETOSPEED®-MR can increase blood pressure in some people, especially in high doses, and your doctor will want to check your blood pressure from time to time.
- You have any history of liver or kidney disease.
- You are being treated for an infection. ETOSPEED®-MR can mask or hide a fever, which is a sign of infection.
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years of age.

If you are not sure if any of the above apply to you, talk to your doctor before taking ETOSPEED®-MR to see if this medicine is suitable for you.

ETOSPEED®-MR works equally well in older and younger adult patients. If you are over 65 years of age, your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for patients over 65 years of age.

## **Children**

Do not give this medicine to children.

## **Other medicines and ETOSPEED®-MR**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines 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 ETOSPEED®-MR:

- Medicines that thin your blood (anticoagulants), such as warfarin
- Rifampicin (an antibiotic)
- Methotrexate (a drug used for suppressing the immune system, used in rheumatoid arthritis)
- Ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- Lithium (a medicine used to treat some types of depression)
- medicines used to help control high blood pressure and heart failure called ACE inhibitors angiotensin receptor blockers, examples include enalapril/ ramipril, and losartan, valsartan
- Diuretics (water tablets)
- Digoxin (a medicine for heart failure and irregular heart rhythm)
- Minoxidil (a drug used to treat high blood pressure)
- Salbutamol tablets or oral solution (a medicine for asthma)
- Birth control pills (the combination may increase your risk of side effects)
- Hormone replacement therapy (the combination may increase your risk of side effects)
- Aspirin, the risk of stomach ulcers is greater if you take ETOSPEED®-MR with aspirin.
- Aspirin for prevention of heart attacks or stroke:

ETOSPEED®-MR can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor - aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs): do not take high dose aspirin or other anti-inflammatory medicines while taking ETOSPEED®-MR. The dose must be reduced in case of presence of diarrhoea following oral administration.

After administration by intramuscular route episodes were observed of vasovagal syncope, thus the patient has to be monitored after being injected.

Post marketing cases of cytolytic hepatitis and cholestatic were reported with Thiocolchicoside.

The serious cases (for example fulminant hepatitis) were observed in patients that had taken FANS or paracetamol at the same time. The patients have to be informed to report any sign of hepatic toxicity.

Thiocolchicoside may precipitate seizures especially in epileptic patients or those at risk of convulsions.

The maximum daily oral dose of 16mg must not be exceeded and must be split in two doses at 12-hour interval.

In case you forget to take a dose take the next dose avoiding taking doses close to each other.

Preclinical studies showed that one of Thiocolcoside metabolites (SL59.0955) induced aneuploidy (i.e. alterations in the number of chromosomes in dividing cells) at concentrations close to human exposure observed at doses 8 mg twice daily per os. Aneuploidy is considered as a risk factor for teratogenicity, embryo/foetotoxicity, spontaneous abortion, and impaired male fertility and a potential risk factor for cancer. As a precautionary measure, use of the product at doses exceeding the recommended dose or long-term use should be avoided. Patients should be carefully informed about the potential risk of a possible pregnancy and about effective contraception measures to be followed.

### **ETOSPEED®-MR with food and drink**

The onset of the effect of ETOSPEED®-MR may be faster when taken without food.

### **Pregnancy**

ETOSPEED®-MR Tablets must 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. Consult your doctor if you are unsure or need more advice.

### **Breast-feeding**

It is not known if ETOSPEED®-MR is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking ETOXIB MR. If you are using ETOSPEED®-MR, you must not breast-feed.

### **Fertility**

ETOSPEED®-MR is not recommended in women attempting to become pregnant.

### **Driving and using machines**

Dizziness and sleepiness have been reported in some patients taking ETOXIB MR.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

## **3. How to take ETOSPEED®-MR?**

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

Do not take more than the recommended dose for your condition. Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain and you should not take ETOSPEED®-MR for longer than necessary.

This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

There are different strengths available for this medicinal product and depending on your disease your, doctor will prescribe the tablet strength that is appropriate for you.

The recommended dose is: One table of ETOSPEED-MR one or two times daily or as prescribed by the healthcare professional depending on the severity of the condition being treated.

### **Use in children**

ETOSPEED-MR is **NOT** suitable for children.

### **If you take more ETOSPEED-MR than you should**

You should never take more tablets than the doctor recommends. If you do take too many ETOXIB MR Tablets, you should seek medical attention immediately.

### **If you forget to take ETOSPEED-MR**

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose

- **Do not take a double dose to make up for a forgotten dose**

If you stop taking ETOSPEED-MR

Do not stop taking Sucralfate Suspension without talking to your doctor.

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

## **4. Possible side effects?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you develop any of these signs you should stop ETOSPEED-MR and talk to your doctor immediately (see what you need to know before you take ETOSPEED-MR section

- Shortness of breath, chest pains, or ankle swelling appear or if they get worse
- yellowing of the skin and eyes (jaundice) – these are signs of liver problems
- Severe or continual stomach pain or your stools become black
- an allergic reaction- which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing The frequency of possible side effects listed below is defined using the following convention:

The following side effects can occur during treatment with ETOXIB MR:

**Very Common:** Stomach pain

**Common:**

- Dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- Dizziness, headache

- Palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia)
- increased blood pressure
- Wheezing or shortness of breath (bronchospasms)
- Constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), Heartburn, diarrhoea, indigestion (dyspepsia)/stomach discomfort, nausea, being sick (vomiting), Inflammation of the oesophagus, mouth ulcers
- Changes in blood tests related to your liver
- Bruising
- Weakness and fatigue, flu-like illness

**Uncommon:**

- Gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection
- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, platelets decreased)
- Hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
- Appetite increases or decreases, weight gain
- Anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing thing that are not there (hallucinations)
- Taste alteration, inability to sleep, numbness or tingling, sleepiness
- Blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack
- flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels
- cough, breathlessness, nose bleed
- stomach or bowel bloating, changes in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas
- swelling of the face, skin rash or itchy skin, redness of the skin
- Muscle cramp/spasm, muscle pain/stiffness
- High levels of potassium in your blood, changes in blood or urine tests relating to your kidney, serious kidney problems
- Chest pain

**Rare:**

- Angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may Cause difficulty in breathing or swallowing, which may be serious enough to require immediate medical attention)/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention)
- Confusion, restlessness
- Liver problems (hepatitis)
- Low blood levels of sodium
- Liver failure, yellowing of the skin and/or eyes (jaundice)
- Severe skin reactions

**Disturbances in immunity system**

Anaphylactic reactions:

Uncommon: pruritis,

Rare: urticarial

Very rare: hypotension

Not noted: angioedema and anaphylactic shock after intramuscular administration.

**Pathology of the nervous system**

Common: drowsiness

Rare: agitation and clouding

Not noted: malaise associated or to a lesser extent vasovagal syncope in the minutes following intramuscular administration, convulsions.

**Gastrointestinal pathology**

Common: diarrhoea, stomach pain

Uncommon: nausea, vomiting

Rare: heartburn after oral administration

**Hepatobiliary pathology**

Not noted: cytolytic hepatitis and cholestatic.

**Pathology of the skin and subcutaneous tissue**

Uncommon: allergic skin reactions

**Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab “Safety Reporting” located on the top of the home page.

<https://www.zuventus.co.in/drug-safety-reporting>

By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store ETOSPEED-MR.**

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

Keep all medicine out of reach of children.

## **6. Contents of the pack and other information**

### **What ETOSPEED-MR contains**

Composition:

Each film coated tablet contains:

Etoricoxib IP 60 mg

Thiocolchicoside IP 4 mg

Colours: Red Oxide of Iron & Titanium Dioxide IP

### **Packaging information**

1blister strip of 10 tablets each

### **Marketing Authorisation Holder**

Zuventus Healthcare Limited

Zuventus House Plot No. Y2, CTS No: 358/A2,  
near Nahur Railway Station, off Raycon IT Park Road,  
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