

ZOLTEROL SR TABLET

Diclofenac Sodium (75mg, 100mg)

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What Zolterol is used for

Zolterol belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation as listed below.

Indicated for treatment of:

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis (systemic inflammatory disorder that affects joints), ankylosing spondylitis (chronic inflammatory disease of the skeleton), osteoarthritis (degenerative joint disease) and spondylarthritis (inflammation of the joint), painful syndromes of the vertebral column, non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints).
- Post-traumatic and post-operative pain, inflammation and swelling.
- Primary dysmenorrhea (period pain)

How Zolterol works

Zolterol relieves the symptoms of inflammation, such as pain and swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

Before you use Zolterol

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it

- If you are allergic (hypersensitive) to diclofenac or to any of the other ingredients of Zolterol listed at the end of this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema). If you think you may be allergic, ask your doctor for advice.
- If you have stomach or intestinal ulcer.
- If you have gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.
- If you suffer from kidney or liver failure.
- If you suffer from severe heart failure.
- If you are in the last three months of pregnancy.

If any of these apply to you, tell your doctor before receiving/taking/using Zolterol.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or think that you may be pregnant. You should not receive/take/use Zolterol in any form while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not receive/take/use Zolterol in any form during the last 3 months of pregnancy, as it could harm your unborn child and cause problems at delivery.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are receiving/taking/using Zolterol, as it might be harmful for your infant.

Your doctor will discuss with you the potential risk of receiving/taking/using Zolterol during pregnancy or breast-feeding.

Females of child-bearing potential

Zolterol may make it more difficult to become pregnant. You should not take Zolterol unless necessary, if you are planning to become pregnant or if you have problems to become pregnant.

- Before you start to use it

Warning and precautions

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), treatment with Zolterol is generally not recommended.
- If you have established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Zolterol, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- It is generally important to take the lowest dose of Zolterol that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- If you are receiving/taking/using Zolterol simultaneously with other anti-inflammatory medicines including acetylsalicylic acid, corticosteroids, “blood thinners” or selective serotonin-reuptake inhibitors.
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had gastrointestinal problems such as stomach ulcer, bleeding or black

stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.

- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn's disease).
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhea, before or after major surgery).
- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract as taking Zolterol can sometimes worsen wound healing in your gut after surgery.

If any of these apply to you, tell your doctor before you receive/take/use Zolterol in any form.

Older people

Elderly patients, especially those who are frail or with a low body weight, may be more sensitive to the effects of Zolterol than other adults. They should follow the doctor's instruction particularly carefully and take the lowest dose for their condition. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children and adolescents

Zolterol SR tablets must not be given to children and adolescents (below 18 years of age).

- Taking other medicines

Tell your doctor, pharmacist or healthcare provider, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (medicines used to treat some types of depression).

- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- "Blood thinners" (medicines used to prevent blood-clotting).
- Medicines (such as metformin) used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibacterials (medicines used against infections).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections)

How to use Zolterol

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

- How much to use

Dose to be individually adjusted, lowest effective dose to be given for the shortest duration.

Adults: 100 to 150 mg/day initially. For milder cases, 75 to 100mg daily is usually sufficient.

Where the symptoms are most pronounced during the night or in the morning, Zolterol prolonged-release 75mg and 100mg should preferably be taken in the evening.

Pediatrics (below 18 years of age): Because of their dosage

strength, Zolterol SR tablets 75mg and 100mg are not suitable for children and adolescents.

Geriatrics (Patients aged 65 or above): No adjustment of the starting dose is generally required. However, caution is indicated on basic medical grounds, especially for frail elderly patients or those with a low body weight.

- When to use it

The tablets should be swallowed whole with liquid, preferably with meals and must not be divided or chewed.

- How long to use Zolterol

Follow your doctor's instructions exactly.

If you take Zolterol for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

If you have questions about how long to take Zolterol, talk to your doctor or your pharmacist.

- If you forget to use Zolterol

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take the next tablet at the usual time. Do not double the next dose to make up for the one you missed.

- If you use too much (overdose)

If you have accidentally taken too much Zolterol, tell your doctor or pharmacist or go to the hospital emergency unit at once.

You may require medical attention.

While you are using Zolterol

- Things you must do

- If, at any time while taking Zolterol you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.
- Zolterol may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the

infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are receiving/taking Zolterol.

- In very rare cases, Zolterol, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash).

If you get any of the above described symptoms, tell your doctor straight away.

- ***Things you must not do***

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Zolterol to anyone else, even if they have the same symptoms or condition as you.

- ***Things to be careful of***

Driving and using machines

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

Monitoring during your treatment with Zolterol

If you have established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Zolterol, especially in case you are treated for more than 4 weeks.

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Zolterol needs to be discontinued or if the dose needs to be changed.

Side effects

As with all medicines, patients taking Zolterol can experience side effects, although not everybody gets them.

Some side effects could be serious

Uncommon: *may affect up to 1 in every 100 patients, especially taking a high daily dose (150mg) for a long period of time*

- Sudden and oppressive chest pain (signs of myocardial infarction or heart attack).
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

Rare or very rare: *may affect up to 1 in every 1,000 patients or up to 1 in every 10,000 patients*

- Spontaneous bleeding or bruising (signs of thrombocytopenia).
- High fever, frequent infections, persistent sore throat (signs of agranulocytosis).
- Difficulty of breathing or swallowing, rash, itching, hives, dizziness (signs of hypersensitivity, anaphylactic and anaphylactoid reactions).
- Swelling mainly of the face and throat (signs of angioedema).
- Disturbing thoughts or moods (signs of psychotic disorders).
- Impaired memory (signs of memory impairment).
- Seizures (signs of convulsions).
- Anxiety.
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of limbs or face (signs of cerebrovascular accident or stroke).
- Difficulty of hearing (signs of impaired hearing).
- Headache, dizziness (signs of high blood pressure, hypertension).
- Rash, purplish-red spots, fever, itching (signs of vasculitis).
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or Pneumonitis if fever).

- Vomiting of blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal hemorrhage).
- Bloody diarrhea (signs of hemorrhagic diarrhea).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer, bleeding or perforation).
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease).
- Severe upper stomach pain (signs of pancreatitis).
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure).
- Flu-like symptoms, feeling tired, muscles aches, increased liver enzymes in blood test results (signs of liver disorders including fulminant hepatitis, hepatic necrosis, hepatic failure).
- Blister (signs of bullous dermatitis).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling (signs of erythema multiforme or if fever signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Skin rash with flaking or peeling (signs of exfoliative dermatitis).
- Increased sensitivity of the skin to sun (signs of photosensitivity reaction).
- Purple skin patches (signs of purpura or Hensch-Schoenlein purpura if caused by an allergy).
- Swelling, feeling weak, or abnormal urination (signs of acute renal failure).
- Excess of protein in the urine (signs of proteinuria).

- Swollen face or abdomen, high blood pressure (signs of nephrotic syndrome).
- Higher or lower urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis).
- Severely decreased urine output (signs of renal papillary necrosis).
- Generalized swelling (signs of edema).

Frequency “not known”: Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

If you experience any of these, tell your doctor straight away.

Other possible side effects

Common: may affect up to 1 in every 10 people

Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia (indigestion), abdominal pain, flatulence, decreased appetite, transaminases increased, rash

Uncommon: may affect up to 1 in every 100 people

Palpitations, chest pain

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my (Consumer →Reporting Side Effects to Medicines (ConSERF)).

Storage and disposal of Zolterol

- Storage

- Protect from moisture and heat.
- Keep below 30°C in a cool dry place
- Keep out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. 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

Zolterol SR tablets are available in two strengths:

Zolterol SR Tablets 75 mg: Pale pink, triangular, film coated tablet, plain on both sides.

Zolterol SR Tablets 100 mg: Pale pink, round, film coated tablet, plain on both sides.

- Ingredients

Active ingredient:

- Diclofenac sodium.

Inactive ingredients:

- Hydroxypropyl cellulose
- Lactose monohydrate
- Magnesium stearate
- Fumed silicon dioxide
- Microcrystalline cellulose
- Glyceryl behenate
- Opadry pink

- MAL Number

Zolterol SR Tablet 75mg:
MAL04125505AZ

Zolterol SR Tablet 100mg:
MAL04125504AZ

Manufacturer:

Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Product Registration Holder

Duopharma Marketing Sdn. Bhd.

Lot No. 2,4,6,8 &10, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

Date of Revision

11/09/2025

Serial Number:

NPRA(R2/1)260206/00016