

Package leaflet: Information for the patient

Sulindac 100 mg and 200 mg Tablets (sulindac)

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 effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Sulindac is and what it is used for

Sulindac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is a painkiller and antipyretic (reduces fever). Sulindac works by reducing inflammation and relieving pain, swelling and stiffness in the joints and muscles. There are a number of painful conditions that can affect your joints and muscles, which can be helped by taking Sulindac. These conditions include:

- Rheumatoid arthritis
- Osteoarthritis
- Ankylosing spondylitis (arthritis in the spine)
- Gout
- Musculo-skeletal disorders such as sprains, strains and other injuries.

2. What you need to know before you take Sulindac

Do not take Sulindac if you

- are allergic to sulindac or any of the other ingredients of this medicine (listed in section 6)
- have taken an NSAID in the past (e.g. ibuprofen, aspirin) and suffered an allergic reaction or had problems such as bleeding or ulcers
- have a stomach or gut ulcer, bleeding in your stomach or know that you have suffered with ulcers, stomach bleeding or perforation in the past
- have severe heart failure
- have severe liver or kidney problems
- are already taking an NSAID eg. celecoxib, etoricoxib, naproxen
- are in the last three months of pregnancy (please read the 'Pregnancy and breast-feeding' section of this leaflet).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- suffer from or have a history of asthma
- have any problems with your stomach or bowel e.g. ulcerative colitis, Crohn's disease
- have had bleeding problems

- have a history of high blood pressure and/or shortness of breath and swelling of the feet or legs due to fluid build up
- have problems with your heart, liver or kidneys; your doctor will monitor your kidney function regularly
- have a collagen vascular disease e.g. lupus (SLE).

Please note:

Medicines such as Sulindac may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Discuss your treatment with the doctor before taking Sulindac:

- if you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”)
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Your doctor will want to ensure that you take the lowest necessary dose of Sulindac for the shortest period necessary.

Other medicines and Sulindac

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

- anticoagulants to thin your blood, such as warfarin; as the level of all the medicine in your blood may increase when you start taking Sulindac
- diuretics (water tablets), as these may not work as well when you start taking Sulindac
- medicines to lower your blood pressure or to treat a heart condition e.g. digoxin
- lithium to treat mental illness or methotrexate, for psoriasis, as your body may not be able to clear these as quickly when you start taking Sulindac
- medicines to treat depression called selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, citalopram
- probenecid, for gout, as the dose of Sulindac you will need will be lower than usual
- antibiotics to treat infection e.g. ofloxacin, as side effects may occur if some antibiotics are taken with Sulindac
- corticosteroids such as prednisolone
- immunosuppressants such as ciclosporin, tacrolimus
- mifepristone (taken in the last 12 days)
- dimethyl sulfoxide, which may also be an ingredient in some medicines
- zidovudine to treat HIV infection

Pregnancy, breast-feeding and fertility

Sulindac **should not** be taken in the last three months of pregnancy as it can affect the growth of your unborn baby and may also affect your labour. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby’s tendency to bleed and cause labour to be later or longer than expected. You should not take Sulindac during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Sulindac can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. If you are trying to get pregnant, Sulindac may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Do not breast-feed your baby, as small amounts of sulindac can pass into breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or use machinery if you suffer from side effects such as dizziness, drowsiness, fatigue and visual disturbances.

Sulindac contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Sulindac

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

Swallow the tablets with a glass of water, with or after food.
The tablet can be divided into equal doses.

Adults

The recommended dose is up to 400 mg a day, divided into two doses. The length of treatment for gout is usually 7 days and for joint swelling and pain, treatment should be no longer than 10 days.

Older people

If you are an older person the dose you take will be similar to other adults but should be the lowest dose that is effective. If you notice any signs of bleeding in your stomach or gut (e.g. black, tarry stools or if you vomit blood) stop taking Sulindac and tell your doctor straight away.

Use in children

Sulindac should not be given to children.

If you take more Sulindac than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include drowsiness, dizziness, heartburn, indigestion, feeling and being sick, diarrhoea, feeling disorientated or highly excited, ringing in the ear, fits, fainting and a reduction in urine output.

If you forget to take Sulindac

Take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Sulindac

Do not stop taking Sulindac without talking to your doctor, even if you feel better. It is important that you take the full course of your treatment prescribed by your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are more likely in older patients.

If any of the following happen, **stop taking Sulindac and tell your doctor immediately** or go to your nearest hospital emergency department:

- if you have severe stomach pain
- if you pass blood in your faeces (stools/motions)
- if you pass black, tarry stools
- if you vomit any blood or dark particles that look like coffee grounds
- if you have an allergic reaction causing difficulty in breathing, tightness of the chest, swelling of the face, throat or tongue, nose bleeds, sore, dry or itchy skin
- if you have severe skin reactions causing rash, red patches or blistering of the skin, mouth, eyes or genitals
- if you notice sensitivity of the skin to sunlight, red spots or rash on the skin or unusual bruising or bleeding of the skin
- if your skin or the whites of your eyes become yellow
- if you have severe upper stomach pain often with feeling or being sick (signs of inflammation of the pancreas)
- if you have fits
- if you are feeling unusually tired and pale, feverish, have a sore throat, suffer from more infections than usual

Stop taking the medicine and tell your doctor if you experience:

- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Medicines such as Sulindac may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

There have been reports of patients suffering from a mild form of meningitis (causing headache, a stiff neck, fever, confusion, feeling or being sick). This is more likely in patients with a collagen vascular disease such as lupus (SLE).

The most commonly seen side effects affect the stomach or gut and they include feeling or being sick, loss of appetite, diarrhoea, wind, constipation, stomach cramps or pain, indigestion, mouth ulcers, a sore swollen mouth and worsening of symptoms in patients with ulcerative colitis, Crohn’s disease or other gut disorder.

Other less common side effects are:

- liver problems which may cause dark urine, pale stools
- severe stomach upset (gastritis)
- change in urinary function such as difficulty or pain in passing urine, blood, protein or crystals forming in the urine, change in urine colour
- swollen ankles and breathlessness, a racing or irregular heart beat
- vaginal bleeding, swollen breasts (in men)
- vertigo, feeling drowsy or tired, sleeplessness
- tingling or numbness in the arms and legs
- headache, fainting,
- feeling dizzy, nervous, confused, depressed, weak or generally unwell
- hallucinating, ringing in the ears
- aggressive or abnormal behaviour, mood changes, sweating
- loss of hearing, hair loss
- bitter or metallic taste in the mouth
- raised blood pressure
- high levels of potassium or glucose in the blood
- rarely, swollen red sore skin (vasculitis)
- changes in your eye sight; Tell your doctor if you suffer from loss of vision or blurred vision. You may need an eye examination.

Patients on medicine to thin the blood e.g. warfarin, may need their dose adjusted.

Reporting of side effects.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sulindac

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is shown on the label or carton. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Sulindac contains**

The active substance is sulindac. Each tablet contains 100 mg or 200 mg of sulindac.

The other ingredients are lactose (see section 2, 'Sulindac contains lactose'), microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, talc and quinoline yellow (E104).

What Sulindac looks like and contents of the pack

Your medicine comes as orange-yellow tablets. The 100 mg tablets are marked 'SD/100' on one side and 'α' on the other. The 200 mg tablets are marked 'SD/200' on one side and 'α' on the other.

Sulindac is available in plastic bottles or blister packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50 (bottles only), 56, 60, 84, 90, 100, 112, 120, 168, 180, 200 (bottles only) and 500 (bottles only) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire EN6 1TL, United Kingdom

Manufacturers:

Generics (UK) Limited, Potters Bar, Hertfordshire EN6 1TL, United Kingdom

Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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