

Package Leaflet: Information for the user

SURGAM 300 mg Tablets

tiaprofenic acid

Is this leaflet hard to see or read? Phone 0121 468 2134 for help

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

1. What SURGAM is and what it is used for

The name of your medicine is SURGAM 300 mg Tablets (called SURGAM in this leaflet).

SURGAM contains a medicine called tiaprofenic acid. This belongs to a group of medicines called 'non-steroidal anti-inflammatory drugs' (NSAIDs). It works by blocking some chemicals in your body that normally cause inflammation.

It is used to treat the swelling, pain, heat, redness and stiffness in your joints and muscles in the following:

- Rheumatoid arthritis (inflammation of the joints)
- Osteoarthritis (where the cushioning (cartilage) between the bone joints is damaged)
- Lower back pain
- Sprains and strains
- Pain and inflammation after an operation
- Other painful inflammatory joint or muscle problems

2. What you need to know before you take SURGAM

Do not take this medicine and tell your doctor if:

- X You are allergic to tiaprofenic acid or any of the other ingredients of this medicine listed in section 6.
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- X You are allergic (hypersensitive) to any other similar medicines (non-steroidal anti-inflammatory drugs or NSAIDs) such as aspirin or ibuprofen.
- X You have or ever had an ulcer (burning, aching pain with an empty feeling and hunger) or bleeding in your stomach or gut.
- X You have or ever had asthma.

- X You have severe heart problems.
- X You have kidney or liver problems.
- X You have or ever had problems passing water (urine) such as pain, blood in your urine or passing water more often than usual.
- X You are in the last three months of pregnancy (see ‘pregnancy and breast-feeding’ below).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking SURGAM.

Warnings and precautions

Talk to your doctor or pharmacist before taking SURGAM if:

- You often have or ever had something called ‘rhinitis’ (runny nose, itching, sneezing and stuffy nose – for example if you have hayfever).
- You often have or ever had something called ‘urticaria’ (itchy lumpy rash).
- You have ulcerative colitis or Crohn’s disease.
- You have a disease affecting the skin, joints or kidney called ‘Systemic Lupus Erythematosus’ (SLE).
- You are elderly.
- You have blood problems (such as unusual bruising or bleeding).
- You have ever had high blood pressure (hypertension).
- You have ever had heart problems such as a stroke.
- You have diabetes.
- You have ever had a high cholesterol level.
- You are a smoker.
- You think you might be at risk of heart problems such as stroke.
- You are having or have had heart bypass surgery.
- You are in the first six months of pregnancy (see ‘pregnancy and breast-feeding’ below).
- You are planning to become pregnant or you have problems becoming pregnant. SURGAM may make it more difficult to become pregnant.

Children and adolescents

SURGAM is not recommended for use in children and adolescents because their safety and efficacy has not yet been established.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking SURGAM.

Other medicines and SURGAM

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because SURGAM can affect the way some other medicines work. Also some medicines can affect the way SURGAM works.

In particular, tell your doctor if you are taking any of the following:

- Other non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen, celecoxib, etodolac or meloxicam
- Water tablets (diuretics) such as spironolactone, triamterene or amiloride used to increase the flow of your water (urine)
- Antibiotics such as quinolone, sulphonamides or aminoglycosides (for infections)
- Corticosteroids such as prednisolone (for inflammation, allergies or some types of cancer)
- Medicines for lowering your blood sugar such as medicines for diabetes
- Medicines for lowering your blood pressure (antihypertensives)
- Medicines called ‘cardiac glycosides’ such as digoxin (for heart failure)

- Medicine to stop your blood clotting such as heparin, warfarin, clopidogrel, ticlopidine, dabigatran, apixaban, rivaroxaban or edoxaban
- Medicine to dissolve blood clots such as streptokinase, alteplase, reteplase or tenecteplase
- Pentoxifylline – used to increase blood flow to arms and legs
- Ciclosporin – used after an organ transplantation to help prevent rejection
- Medicines for depression such as fluoxetine, sertraline, citalopram or paroxetine
- Mifepristone – for terminating a pregnancy. It is important not to use SURGAM for at least 8-12 days after taking mifepristone.
- Lithium – for some types of mental illness
- Phenytoin – for epilepsy
- Methotrexate – for some types of cancer
- Tenofovir – an antiretroviral medicine which is used to treat HIV infection
- Probenecid – used with a medicine called cidofovir to stop kidney damage
- Tacrolimus – used after an organ transplant
- Zidovudine – an antiretroviral drug
- Nicorandil – used for treating chest pain

Please tell your doctor if you are taking any of these medicines.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant.
- You are breast-feeding or planning to breast-feed.

Do not take Surgam if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. 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 Surgam 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, Surgam 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.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

Driving and using machines

You may feel sleepy, dizzy, faint or your eyesight may be affected while taking this medicine. If this happens, do not drive or use any tools or machines.

3. How to take SURGAM

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

Taking this medicine

- Take this medicine by mouth
- Take with or after food
- Swallow the tablets whole with a drink of water
- Do not crush or chew your tablets

- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

Adults

The usual dose of SURGAM is 1 tablet twice a day.

Children

SURGAM is not recommended for children.

The elderly (over 65 years)

You are more likely to get side effects while taking SURGAM. Your doctor may lower the number of tablets that you take.

If you take more SURGAM than you should

If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. High doses of SURGAM and prolonged treatment can increase the chances of you having a heart attack or stroke (see Section 4: Possible side effects). Do not exceed the recommended dose or duration of treatment.

If you forget to take SURGAM

If you forget a dose, take it as soon as you remember. 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 tablet.

If you stop taking SURGAM

Keep taking your medicine until your doctor tells you to stop. Do not stop taking SURGAM just because you feel better. If you stop, your illness may get worse.

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.

Stop taking and see your doctor or go to a hospital straight away if:

- You have an **allergic reaction**. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have difficulty breathing, wheezing, tightness in the chest (something called ‘bronchospasm’)
- Your asthma is getting worse – this may be a sign of an allergic reaction
- You have a heart attack (myocardial infarction) or stroke. Medicines such as SURGAM may be associated with a small increased risk of heart attack, stroke or heart failure (see section 3).
- You have blistering or bleeding of the skin around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called ‘Stevens-Johnson syndrome’.
- You have a severe blistering rash where layers of your skin may have peeled off to leave large areas of raw exposed skin over your body. Also, you may feel generally unwell, with a fever, chills and aching muscles. This may be something called ‘Toxic epidermal necrolysis’.
- You are vomiting any blood or dark particles that look like coffee grounds, have severe stomach pains or pass blood in your stools (faeces) or have dark tarry stools. These are signs of an ulcer that has made tiny holes in your stomach or gut that are bleeding.
- You have a burning, aching pain in your stomach, with an empty feeling and hunger. You may have an ulcer in your stomach or gut.
- You feel pain when passing water (urine), have to pass water more often than usual, have blood in your urine as you may have swelling of the bladder

- Your limbs are swollen (signs of fluid retention), you feel tired (fatigued) and generally unwell. You may have kidney problems which, if untreated, could become very serious.

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (may affect more than 1 in 10 people)

- Abdominal pain upper

Frequency not known (cannot be estimated from the available data)

- Severe stomach pain, which may reach through to your back. This could be a sign of pancreatitis.
- A stomach problem which may result in pain, nausea, vomiting, vomiting blood, and blood in the bowel motions. This may be something called gastritis.
- You have worsening of your Crohn's disease or colitis
- You have a skin reaction to light or sunlamps (photosensitivity)
- You have skin reactions such as itchy, lumpy rash ('urticaria')
- Your eyes or skin go yellow (jaundice). This may be a sign of liver problems. You may have something called 'hepatitis'. This would also show up in the results of some blood tests.
- You bruise more easily than usual or have bleeding that lasts a long time
- You have more infections than usual. This could be because of blood disorders called 'agranulocytosis' or 'neutropenia'.
- You feel tired, faint, dizzy and have pale skin (anaemia)
- You have pain in your eyes (optic neuritis)
- You have problems with your eyesight
- You feel depressed, confused or are having hallucinations
- You have one or more of the following symptoms: stiff neck, headache, nausea, vomiting, fever or disorientation

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.

Common (may affect up to 1 in 10 people)

- Feeling sick (nausea), being sick (vomiting) or diarrhoea
- Dizziness

Frequency not known (cannot be estimated from the available data)

- You have itching ('pruritus')
- You have skin reactions such as redness, blood spots ('purpura'), or hair loss, balding ('alopecia')
- Pain in your lower stomach, back or groin often worse before needing to pass urine
- Pain when passing water (urine), have to pass water more often than usual or have blood in your urine
- Indigestion, heartburn, stomach pain, constipation or wind (flatulence)
- Abnormal liver function test
- Decreased appetite (loss of appetite)
- Swelling in mouth
- Headaches
- Drowsiness, dizziness or ringing in the ears (tinnitus)
- Pins and needles (something called 'paraesthesia')
- Tiredness
- Feeling unwell
- Fluid retention which may cause swollen arms or legs
- High blood pressure

- Feeling like things around you are moving or spinning, feeling dizzy or have difficulty balancing (vertigo)

These side effects may go away during treatment as your body gets used to the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store SURGAM

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Keep the blister strip in the outer carton in order to protect from light. Do not transfer your medicine to another container.

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 to protect the environment.

6. Contents of the pack and other information

What SURGAM contains

Each tablet contains 300 mg of the active substance, tiaprofenic acid

The other ingredients are maize starch, poloxamer, magnesium stearate and purified talc

What SURGAM looks like and contents of the pack

SURGAM tablets are white to creamy white biconvex tablets with the Roussel logo on one side and a breakline on the other side. 'Surgam' and '300' are embossed on the tablet. They are available in blister packs of 56 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Fidia Pharma UK Ltd,
170 Edmund Street, Ground Floor
Birmingham, B3 2HB, UK
Tel: 0121 468 2143
email: medinfo@fidiapharma.it

Manufacturer

Opella Healthcare International SAS,
56 Route de Choisy
60200 Compiègne, France

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