

Surgam® 100 mg scored tablets

tiaprofenic acid

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. Further information

1. WHAT SURGAM IS AND WHAT IT IS USED FOR

ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

This medicine is intended for use in adults and children weighing at least 15 kg (i.e. from approximately 4 years of age):

- for long-term treatment of:
 - certain forms of chronic inflammatory rheumatism (a condition involving inflammation of the joints),
 - certain forms of severe osteoarthritis (damaged cushioning (cartilage) between the bone joints),
- for short-term treatment of:
 - acute pain due to osteoarthritis,
 - acute lower back pain,
 - pain and edema (abnormal accumulation of fluid that produces swelling) as a result of trauma,
- for menstrual pain,
- for treatment of painful conditions due to inflammation in certain parts of the body (throat, ear, mouth, nose).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SURGAM

Do not use Surgam:

- if you are more than 5 months pregnant (24 weeks since last menstrual period),
- if you have ever had allergy or asthma caused by this medicine or any other similar drug, particularly other non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin,
- if you have ever had an allergic reaction to one of the ingredients in the tablet,
- if you have ever had bleeding in your stomach or gut or an ulcer (burning, aching pain with an empty feeling and hunger) caused by previous use of non-steroidal anti-inflammatory drugs,
- if you have ever had an ulcer or suffer from active or recurrent ulcers in the stomach or in the first portion of the small intestine (duodenum),
- if you have bleeding in your stomach or gut, bleeding in the brain or any other bleeding problems,
- if you have serious liver disease,
- if you have serious kidney disease,
- if you have serious heart disease,
- if your child does not weigh at least 15 kg, i.e. is approximately 4 years of age (because of inappropriate dosage strength).

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Surgam

Special warnings

Medicines such as **Surgam** may increase the risk of heart attack ("myocardial infarction") or stroke. This risk increases when the medicine is taken at high doses over long periods of time. Do not take more tablets than you have been told to or take the medicine for longer than recommended.

If you have heart problems, if you have had a stroke or think you may have risk factors for this type of disorder (e.g. if you have high blood pressure, diabetes, high cholesterol levels or if you smoke), talk to your doctor or pharmacist.

THIS MEDICINE MUST ONLY BE TAKEN UNDER MEDICAL SUPERVISION.

BEFORE TREATMENT:

INFORM YOUR DOCTOR:

- if you have ever had asthma along with chronic rhinitis, chronic sinusitis or nasal polyps. Taking this medicine can trigger an asthma attack, particularly in certain people who are allergic to aspirin or to a non-steroidal anti-inflammatory drug (see "Do not take **Surgam**"),

- if you have something called a "dotting disorder"; if you are taking anticoagulants or antiplatelet medicine at the same time. This medicine can have serious effects on your stomach and bowel,
- if you have ever had digestive problems (i.e. a long-standing ulcer in the stomach or duodenum, a "hiatus hernia" or bleeding in your stomach or gut),
- if you have heart, liver or kidney disease,
- if you have an infection. If so, medical supervision should be increased,
- if you have chickenpox. This medicine is not recommended because it can exceptionally cause serious skin infections.

DURING TREATMENT:

- if you have bleeding in your stomach or gut (vomiting blood, bloody stools, dark-colored stools), STOP TREATMENT AND CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE IMMEDIATELY (see section 4 "Possible side effects"),
- if you notice severe skin damage which looks like blisters or burns all over your body STOP TREATMENT AND CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE IMMEDIATELY (see section 4 "Possible side effects"),
- if you have signs of allergy to this medicine, particularly an asthma attack or a sudden swelling of the face and neck, STOP TREATMENT AND IMMEDIATELY CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE (see section 4 "Possible side effects").

Precautions for use

For women: **Surgam** may affect your fertility. Therefore, you should not take this medicine if you are planning to become pregnant, if you have problems becoming pregnant or if you are having fertility tests done.

This medicine is available at other dosage strengths which may be more suitable for you.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Surgam contains a medicine called **tiaprofenic acid** which is a non-steroidal anti-inflammatory drug. You must not take this medicine at the same time as other medicines containing non-steroidal anti-inflammatory drugs (including medicines called "selective cyclooxygenase-2 inhibitors") and/or acetylsalicylic acid (aspirin).

Read the leaflets for any medicines you are taking to make sure they do not contain non-steroidal anti-inflammatory drugs and/or aspirin.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription. This is because some medicines should not be taken together and others may require a change in dose when they are taken together. You must always tell your doctor or pharmacist if you are using or being given any of the following medicines before taking **Surgam**:

- aspirin (acetylsalicylic acid) or any other non-steroidal anti-inflammatory drugs,
- corticosteroids,
- medicines to stop your blood clotting (oral anticoagulants) such as warfarin, injectable heparin, antiplatelet medicines or medicines to dissolve blood clots such as ticlopidine,
- lithium,
- methotrexate,
- angiotensin converting enzyme (ACE) inhibitors, diuretics, beta-blockers and angiotensin II receptor blockers,
- certain antidepressants (selective serotonin reuptake inhibitors),
- pemetrexed,
- ciclosporin, tacrolimus.

Pregnancy

- During the first trimester of pregnancy (12 weeks since last menstrual period, i.e. more specifically, 12 weeks after the first day of your last period), your doctor may need to prescribe this medicine.
- Between 2.5 and 5 full months of pregnancy (12 to 24 weeks since last menstrual period), you should only use this medicine if advised by your doctor and only for a short time. Use of this medicine over prolonged periods of time is absolutely not recommended.
- After 5 full months of pregnancy (after 24 weeks since last menstrual period), you must not take this medicine **under any circumstances** since it may have serious effects on your child, particularly on the heart, lungs and kidneys, even after a single dose. If you have taken this medicine when you were more than five months pregnant, please talk to your obstetrician/gynecologist who will recommend appropriate monitoring.

Breast-feeding

This medicine passes into breast milk. As a precaution, you should avoid using it while breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

In rare cases, this medicine may cause dizziness.

3. HOW TO TAKE Surgam

Dosage

Dosage varies depending on what this medicine is used for.

Adults: dosage is between 3 and 6 tablets of 100 mg, i.e. 300 to 600 mg **maximum** per day.

Children: dosage is based on **bodyweight** and corresponds to 10 mg/kg/day, for example:

- from 15 to 20 kg (approximately 4 to 6 years of age): half a tablet of 100 mg, 3 times per day to 1 tablet of 100 mg, twice a day, i.e. 150 to 200 mg per day;
- between 20 and 30 kg (approximately 6 to 10 years of age): 1 tablet of 100 mg, 2 to 3 times per day, i.e. 200 to 300 mg per day;
- 30 kg or more (i.e. from approximately 10 years of age): 1 tablet of 100 mg, 3 times per day, i.e. 300 mg per day.

Approximate ages according to bodyweight are given as an example.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Method of administration

Take this medicine by mouth.

Tablets should be taken whole with, or dissolved in, a large glass of water.

How often to take Surgam

Tablets should preferably be taken with meals.

Daily doses should be taken as 2 to 3 divided doses.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How long to take Surgam

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you take more Surgam than you should:

In the event of overdose or accidental poisoning, consult a doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Surgam** can cause side effects although not everybody gets them.

Medicines such as **Surgam** can increase the chances of you getting a heart attack ("myocardial infarction") or stroke.

- You may experience the following allergic reactions:
 - skin reactions, rash, urticaria (hives), worsening of long-term urticaria, itching, small spots on the skin, skin reaction when you are exposed to sunlight or UV rays.
Rarely: blister-like skin reactions over your entire body, and sometimes on the mucous membranes (Stevens-Johnson syndrome and Lyell syndrome),
 - breathing problems such as asthma attacks,
 - general : feeling generally unwell and low blood pressure; a certain type of urticaria with sudden swelling of the face and neck (angioedema); allergic shock.
- In rare cases, you may:
 - have bleeding in your stomach or gut (vomiting blood or passing blood in your stools, dark-colored stools). This is more common when taking high doses of **Surgam** over long periods of time,
 - have problems passing water (urine) such as discomfort or pain when urinating, have to pass water more often than usual or have blood in your urine, all of which are reversible once treatment has been stopped.
- Exceptional cases of serious skin infections have been observed in people with chickenpox. If this occurs, you must **stop taking this medicine immediately and inform your doctor.**
- While taking **Surgam**, you may experience the following:
 - edema (abnormal accumulation of fluid that produces swelling), high blood pressure or heart failure,
 - digestive disorders: abdominal pain, vomiting, nausea, diarrhea, transit disorders, indigestion, inflammation of the mouth, worsening of bowel inflammation or Crohn's disease,
 - other effects related to the medicine: dizziness. If this happens, you must inform your doctor.
- Other side effects:
 - cases of ulcers or gastrointestinal perforation (holes in your stomach or gut) or inflammation of the stomach (gastritis) have been observed,

- some rare abnormal laboratory test results may require blood, kidney and liver tests,
 - kidneys: high levels of potassium in the blood (hyperkalemia), kidney disease, kidney function problems,
 - liver: exceptionally, liver function problems,
 - blood: abnormally low levels of platelets (a type of blood cell) which can result in bleeding of the nose or gums.

If you notice any side effects not mentioned in this leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE Surgam

Keep out of the reach and sight of children.
Do not use **Surgam** after the expiry date which is stated on the box.
Store at a temperature no higher than 25°C.
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. FURTHER INFORMATION

What Surgam contains

The active substance is:

Tiaprofenic acid 100 mg
For one scored tablet.

The other ingredients are:

Maize starch, rice starch, pregelatinized maize starch, colloidal anhydrous silica, magnesium stearate, talc.

What Surgam looks like and contents of the pack

This medicine is available as scored tablets in boxes of 30 tablets.

Marketing Authorization Holder and Operating Company

sanofi-aventis France
1-13, boulevard Romain Rolland
75014 Paris – France

Manufacturer

Sanofi Winthrop Industrie
56, route de Choisy au Bac
60205 – Compiègne - France

This leaflet was last approved in August 2012.