

PATIENT INFORMATION LEAFLET

Scheduling status

S2

COPRIN 100 mg Enteric coated tablet

Acetylsalicylic acid.

Sugar free.

Read all of this leaflet carefully before you start taking COPRIN 100 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COPRIN 100 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COPRIN 100 mg is and what it is used for
2. What you need to know before you take COPRIN 100 mg
3. How to take COPRIN 100 mg
4. Possible side effects
5. How to store COPRIN 100 mg
6. Contents of the pack and other information

1. What COPRIN 100 mg is and what it is used for

COPRIN 100 mg contains a medicine called acetylsalicylic acid. It inhibits the adhesion and aggregation of blood platelets (thrombocytes) and in this way prevents the forming of developing blood clots (thrombi).

COPRIN 100 mg is used to prevent heart attack or stroke in patients who have previously suffered from these or are predisposed to these conditions.

2. What you need to know before you take COPRIN 100 mg

Do not take COPRIN 100 mg

- if you are allergic (hypersensitive) to the active ingredient acetylsalicylic acid, other salicylates, or to any of the other ingredients in the tablet (see section 6).
- if you had bronchial asthma related to the use of salicylates or related substances, especially non-steroidal anti-inflammatory medicines.
- if you have a tendency for bleeding.
- if you have gastric or duodenal ulcers.
- if you have kidney problems.
- if you have liver problems.
- if you have a heart condition.
- if you use COPRIN 100 mg concomitantly with methotrexate in doses of 15 mg/week or more.
- if you are in the last trimester of pregnancy (see Pregnancy and breastfeeding).

Warnings and precautions

Take special care with COPRIN 100 mg

- if you have hypersensitivity to analgesics, anti-inflammatory medicines, anti-rheumatic medicines and in the presence of other allergies.

- if you have a history of gastrointestinal ulcers, including chronic or recurrent ulcers or a history of gastrointestinal bleedings. The risk of these side effects are greater with higher doses and in the elderly.
- if you follow a concomitant treatment with other blood thinning medicines.
- if you have impaired kidney function.
- if you have severe liver disease or your liver does not function properly.
- if you have bronchial asthma, hay fever, swelling of nasal mucosa (nasal polyps) or chronic respiratory tract diseases.
- if you need to have surgery (including minor surgical interventions like dental extractions), an increase in bleeding tendency may occur. You may have to stop COPRIN before your procedure.
- if you have gout, as COPRIN may increase the chances of an attack.
- During your menstrual cycle as COPRIN may cause an increase in bleeding.
- if you have a history of hypertension (high blood pressure) and/or heart failure as fluid retention and oedema (swelling) have been reported in association with COPRIN therapy.
- if you have a history of gastrointestinal diseases as the conditions may be worsened.
- COPRIN can cause serious skin reactions. Stop taking COPRIN at the first appearance of skin rash, mouth ulcer or any other allergic reaction.
- COPRIN can cause a reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) which presents with fever, rash, swelling of lymph nodes and glands and/or facial swelling. Contact your doctor or other healthcare provider if you notice any of these symptoms.

Children and adolescents

Children and adolescents should not take COPRIN 100 mg. COPRIN may cause a rare but serious condition called Reye's syndrome in children, especially children who have a viral

infection. Should prolonged vomiting occur with such diseases, this may be a sign of Reye's syndrome, which requires immediate medical attention.

Other medicines and COPRIN 100 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor before taking COPRIN 100 mg if you are already taking any of the following:

- methotrexate (a medicine for the treatment of cancer diseases and certain rheumatic disorders)
- ibuprofen (non-steroidal anti-inflammatory medicine)
- anticoagulants and thrombolytic medicines: COPRIN 100 mg can increase the risk of bleeding if taken before anticoagulant treatment. You should therefore pay attention to signs of external or internal bleeding (e.g. bruising) if they occur during such treatment
- other analgesics and anti-inflammatory medicines (non-steroidal anti-inflammatory medicines) with salicylates at high doses: increased risk of gastrointestinal ulcer and bleeding
- selective serotonin reuptake inhibitors (medicines for depression): increased risk of gastrointestinal bleeding
- digoxin (a medicine that strengthens the cardiac muscle contraction)
- antidiabetics (e.g. insulin, sulphonylureas): the blood sugar levels could decrease
- diuretics (medicine that increase the urine excretion) in combination with acetylsalicylic acid at higher doses
- medicines containing cortisone or cortisone-like substances, with the exception of products that are applied topically or cortisone replacement therapy for Addison's disease: increased risk of gastrointestinal side effects
- certain antihypertensive medicines (ACE inhibitors) in combination with acetylsalicylic acid at higher doses

- valproic acid (medicine for treatment of convulsions of the brain (epilepsy))
- phenytoin (medicine for treatment of epilepsy)
- metamizole (painkiller)
- ciclosporin, tacrolimus (immunosuppressive medicines, medicines that prevent the immune system from damaging healthy cells)
- antacids (medicine to relieve heartburn, indigestion or an upset stomach)
- alcohol: elevated risk of gastrointestinal ulcers and bleeding
- gout remedies that promote the excretion of uric acid (e.g. benzbromarone, probenecid).
- Acetazolamide (medicine for treatment of glaucoma)

Taking COPRIN 100 mg with food and drink

Do not use COPRIN 100 mg with alcohol because it may increase the risk of occurrence of gastrointestinal bleedings.

Pregnancy and breastfeeding

Pregnancy

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

In the first and second trimester of pregnancy, COPRIN 100 mg can be taken only if your doctor has recommended it. In the last trimester of pregnancy, COPRIN 100 mg, should not be taken, due to an increased risk of complications for the mother and baby before and during birth (see also Do not take COPRIN 100 mg).

Breastfeeding

Small quantities of acetylsalicylic acid and its active metabolites pass into the mother's milk. When regular use of COPRIN 100 mg is recommended, breastfeeding should be discontinued.

Driving and using machines

COPRIN 100 mg does not affect the ability to drive or use machines.

It is not always possible to predict to what extent COPRIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which COPRIN affects you.

3. How to take COPRIN 100 mg

Do not share medicines prescribed for you with any other person.

Always take COPRIN 100 mg exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

The usual dose is 100 to 300 mg to be taken every day, preferably at the same time each day.

Take the tablets after meals and swallowed whole with a sufficient quantity of water. Do not crush, break or chew the tablets before swallowing because this will damage the enteric coating.

If you have the impression that COPRIN 100 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more COPRIN 100 mg than you should

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

Dizziness and tinnitus, especially in children and elderly, may indicate severe intoxications. Please tell your doctor if you suspect that you took an overdose of COPRIN 100 mg. If you suspect an overdosage, discontinue the administration of COPRIN 100 mg.

If you forget to take COPRIN 100 mg

If you have forgotten to take a tablet, take it as soon as you remember. However, if it is time for the next dose, skip the missed dose and take your next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

COPRIN 100 mg can have side effects.

Not all side effects reported for COPRIN 100 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COPRIN 100 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens stop taking COPRIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of hands, feet, lips, mouth, throat
- difficulty breathing
- red, itchy rash.

These are all very serious side effects. You may have had a serious reaction to COPRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blood in urine or stool, vomiting blood
- chest pain
- severe headache with nausea, vomiting, dizziness and confusion
- reddening of the skin with blisters or peeling. May be accompanied by a high fever and joint pains
- fever, rash, swelling of lymph nodes and glands and/or facial swelling.

These are all serious side effects. You may need urgent medical attention.

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

Frequent side effects

- stomach pain or discomfort, indigestion or heartburn
- stomach ulcers
- unusual bleeding or bruising
- black stools or severe diarrhoea, flatulence, constipation
- nausea or vomiting
- vomiting blood
- mouth ulcers
- inflammation of intestines or bowel – you may experience rectal bleeding, bloody diarrhoea, abdominal cramps and pain
- dizziness.

Less frequent side effects observed

- runny, stuffy nose
- asthma attack
- increase in the serum values of liver enzymes
- menorrhagia (menstrual bleeding longer than 7 days).

Side effects with unknown frequency

- gout, low blood sugar
- headache, spinning feeling
- reduced hearing, ringing in the ears
- swelling, high blood pressure, heart failure
- impaired kidney function, water retention.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COPRIN 100 mg.

5. How to store COPRIN 100 mg

Store all medicines out of reach of children.

Store at or below 25°C, in the original package. Keep blisters in the carton until required for use.

Do not use COPRIN 100 mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COPRIN 100 mg contains

The active substance is acetylsalicylic acid.

Each COPRIN 100 mg tablet contains 100 mg acetylsalicylic acid.

The other ingredients are: Microcrystalline cellulose, pregelatinized starch, stearic acid, methacrylic acid copolymer, talc, titanium dioxide, triethyl citrate, colloidal anhydrous silica, sodium hydrogen carbonate and sodium lauryl sulphate.

What COPRIN 100 mg looks like and contents of the pack

COPRIN 100 mg tablets are white, round, biconvex tablets with uniform appearance and intact edges.

The film-coated tablets are packed in PVC/Aluminium foil blisters strips containing 10 tablets.

The blister strips are packed in cartons containing 30 or 100 tablets.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

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7570

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