PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ECOTRIN 81 mg enteric coated tablet

Aspirin (acetylsalicylic acid)

Sugar free

Read all of this leaflet carefully before you start taking ECOTRIN

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

1. What ECOTRIN is and what it is used for

ECOTRIN contains aspirin (acetylsalicylic acid), which in low doses belongs to a group of medicines called anti-platelet agents.

ECOTRIN is taken to reduce the risk of blood clots forming and thereby prevent further:

- heart attacks
- strokes
- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

ECOTRIN is also used in the treatment of acute heart attack and to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

2. What you need to know before you take ECOTRIN

Do not take ECOTRIN:

- If you are hypersensitive (allergic) to aspirin (acetylsalicylic acid) or any of the other ingredients of ECOTRIN (listed in section 6).
- If you are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs).
- If you have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs.
- If you currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke.
- If you have ever had the problem of your blood not clotting properly.
- If you have severe liver or kidney problems.
- If you suffer from gout.
- If you have severe heart problems which can cause shortness of breath and ankle swelling.
- If you are in your first or last three months of pregnancy (see section “Pregnancy and breast-feeding”).

- If you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Warnings and precautions

Talk to your doctor or pharmacist before taking ECOTRIN:

- If you have trouble with your kidneys, liver or heart.
- If you have or have ever had problems with your stomach or small intestine.
- If you have uncontrolled high blood pressure.
- If you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; aspirin may induce an asthma attack.
- If you have ever had gout.
- If you have heavy menstrual periods.
- If you suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD).
- If you have had a serious skin reaction to any medicine, accompanied by a fever, swollen or enlarged lymph nodes and/or facial swelling.

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section 4 “Possible side effects”).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since aspirin is blood-thinning there may be an increased risk of bleeding.

Aspirin may cause Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, ECOTRIN should not be given to children aged under 18 years, unless on the advice of a doctor.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of aspirin at the same time may result in deterioration of kidney function.

Children and adolescents

Aspirin should not be administered to children and adolescents younger than 18 years, unless prescribed by a doctor (see section 2 “Warnings and precautions”).

Other medicines and ECOTRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.

The effect of treatment may be influenced if ECOTRIN is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel, alteplase)
- rejection of organ after transplantation (ciclosporin, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- regulation of the heartbeat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen or steroids)
- gout (e.g. probenecid)
- epilepsy (e.g. valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide, insulin)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine)
- use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids)
- antacids (indigestion medicine)
- metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardio protection.

ECOTRIN with food, drink and alcohol

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

ECOTRIN should not be taken during pregnancy unless advised by a doctor.

You should not take ECOTRIN if you are in the first or last 3 months of pregnancy, unless you are advised to do so by your doctor (see section “Do not take ECOTRIN”). Regular or high doses of ECOTRIN during late pregnancy can cause serious complications in the mother or baby.

You should not take ECOTRIN during breastfeeding unless advised by your doctor.

Driving and using machines

ECOTRIN should not affect your ability to drive and use machines.

3. How to take ECOTRIN

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

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

The usual adult dose is:

Adults: One to three tablets as directed by your doctor to be taken every day, preferably at the same time each day.

Your doctor will tell you how long your treatment with ECOTRIN will last. If you have the impression that the effect of ECOTRIN is too strong or too weak, tell your doctor or pharmacist.

If you take more ECOTRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Show any leftover medicines or the empty packet to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take ECOTRIN

If you miss a dose, wait until it is time for your next dose, then go on as normal. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ECOTRIN can have side effects.

Not all side effects reported for ECOTRIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ECOTRIN, please consult your health care provider for advice.

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

- sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ECOTRIN. 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:

- reddening of the skin with blisters or peeling and may be associated with a high fever and

joint pains (this could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome),

- unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools.

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

Tell your doctor if you notice any of the following:

Common side effects (may affect up to 1 in 10 people):

- feeling or being sick, diarrhoea,
- indigestion,
- increased tendency for bleeding.

Uncommon side effects (may affect up to 1 in 100 people):

- hives,
- runny nose,
- breathing difficulty.

Rare side effects (may affect up to 1 in 1,000 people):

- severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells,
- cramps in the lower respiratory tract, asthma attack,
- inflammation in the blood vessels,
- bruising with purple spots (cutaneous bleeding),
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "Children and adolescents"),
- abnormal heavy or prolonged menstrual periods.

Not known (frequency cannot be estimated from the available data)

- ringing in your ears (tinnitus) or reduced hearing ability,
- headache,
- vertigo,
- ulcers in stomach or small intestine and perforation,

- prolonged bleeding time,
- impaired kidney function, acute renal failure,
- salt or water retention which may cause swelling of hands, feet, legs, stomach, breasts or face,
- impaired liver function, increased liver enzymes,
- high level of uric acid in the blood or low levels of sugar in the blood.
- severe skin rash with a fever, swollen or enlarged lymph nodes and/or facial swelling.

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 or pharmacist. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ECOTRIN.

5. How to store ECOTRIN

Store all medicines out of reach of children.

- Store at or below 25 °C in a dry place.
- Do not use after the expiry date stated on the label or carton.

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 ECOTRIN contains

- The active substance is aspirin (acetylsalicylic acid).

Each tablet contains aspirin (acetylsalicylic acid) 81 mg. Sugar free.

- The other ingredients are carnauba wax, corn starch, colloidal silicon dioxide, methacrylic copolymer, microcrystalline cellulose, Opacode monogramming ink black, Opadry clear, Opadry YS-1-6223, orange, propylene glycol, stearic acid, simethicone, triethyl citrate, talc.

What ECOTRIN looks like and contents of the pack

ECOTRIN is a convex, round, orange, coated tablet without any marking.

Contents of the pack:

- 30 ml or 50 ml white HDPE bottles fitted with a white polypropylene screw on cap. A desiccant and foam plug is included in each pack.
- Aluminium/Aluminium blister strips of 10 tablets per strip with 3 blister strips packed in an outer unit carton.

Pack sizes of 30; 50 and 100 tablets.

Holder of Certificate of Registration

ACINO PHARMA (PTY) LTD.

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Access to the corresponding Professional Information

To be confirmed.