SCHEDULING STATUS

S0

ANADIN® TABLETS (400,0 mg **aspirin** and 22,7 mg **caffeine**/ tablet)

Sugar free

Read all of this leaflet carefully because it contains important information for you.

ANADIN tablets is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ANADIN tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANADIN tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- Do not use continuously for pain for more than 10 days or for fever for more than 3 days, unless directed by a doctor. If the pain or fever persists or gets worse, or if new symptoms occur, consult a doctor.

What is in this leaflet

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

1. WHAT ANADIN TABLETS IS AND WHAT IT IS USED FOR

Aspirin, as in ANADIN tablets, is an analgesic (reduces pain), anti-inflammatory (reduces inflammation) and anti-pyretic (reduces fever) agent.

ANADIN tablets are used for the relief of fever and mild to moderate pain such as headache, toothache, period pain, joint pain, muscle pain and pain associated with colds and flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANADIN TABLETS

Do not take ANADIN tablets if you:

- suffer from heartburn or stomach ulcers.
- suffer from any blood disorder (such as haemophilia which is a condition where your blood does not clot well).
- have a history of stomach or intestinal bleeding or perforation due to previous ANADIN, aspirin or non-steroidal anti-inflammatory (medicines that reduce inflammation and pain) treatment.
- suffer from or have suffered from a recurring ulcer, bleeding or perforation of the stomach or intestines.
- have an allergy to ANADIN tablets, to the ingredient aspirin or caffeine or any other xanthine medicine; or an allergy to any non-steroidal anti-inflammatory medicine (medicines that reduce pain and inflammation).
- have an allergy to any other ingredient listed in this leaflet.
- have gout.
- have a severe kidney or liver function problem.
- are taking blood thinners such as warfarin.

Warnings and precautions

Special care should be taken with ANADIN Tablets if you:

- are older than 65 years of age.
- suffer with asthma or other allergic problems.
- suffer from a kidney or liver function problem.
- have lost a lot of body fluid.
- suffer from uncontrolled hypertension (high blood pressure).
- have a glucose-6-phosphate dehydrogenase (G6PD) deficiency (a condition leading to low red blood cell counts).
- are a diabetic.
- are to undergo a thyroid function test.
- are to undergo a surgical procedure within a week of taking ANADIN tablets.
- have a history of stomach or intestinal disease, as the conditions may worsen.
- suffer from or have suffered from heart failure.

Stop taking ANADIN immediately and contact your medical doctor if you experience bloody or black tarry stools.

The aspirin component in ANADIN Tablets has been implicated in Reye's syndrome, a rare but serious illness in children and teenagers, with chicken pox and flu. Therefore, do not give to children under 12 years of age and consult a medical doctor before giving to children between the ages of 12 and 16 years

Other medicines and ANADIN TABLETS:

Always tell your health care provider if you are taking any other medicines.

(This includes complementary or traditional medicines).

Examples of medicines that may cause an undesirable interaction are as follows (caution and consultation with your doctor or pharmacist is advised):

- Blood thinners such as warfarin.
- Oral antidiabetic medicines (medicine you take by mouth for the treatment of diabetes).
- Insulin (medicine you inject for the treatment of diabetes).
- Sulphonamides (medicine used to treat infection).
- Zafirlukast and montelukast: used for asthma.
- Methotrexate: used in cancer patients.
- Phenytoin and valproic acid (medicine used in epilepsy).
- Alcohol.
- Vancomycin (medicine used to treat infection).
- Other non-steroidal anti-inflammatory drugs (medicine used to reduce inflammation i.e. reduces pain and swelling).
- Platelet aggregation inhibitors (medicine used to help prevent the platelets in the blood from clumping together).
- Metoprolol (medicine used to treat high blood pressure).
- Metoclopramide (medicine used for nausea and vomiting.)
- Dipyridamole (medicine used to treat heart or blood conditions).
- Uricosurics (medicine used in the treatment of gout).
- Barbiturates and sedatives (medicine used to induce sleep).
- Corticosteroids.
- Selective serotonin re-uptake inhibitors (medicine used to treat depression).

- Lithium (medicine used to treat bipolar mood disorders).
- Monoamine oxidase inhibitors (medicines used to treat depression).
- Medicines increasing mental alertness

ANADIN TABLETS with food, drink and alcohol

No data available

Pregnancy and breastfeeding and fertility

Pregnancy and Breastfeeding:

ANADIN tablets should not be used during pregnancy and breastfeeding.

The use of ANADIN tablets during the last 3 months of pregnancy can harm your unborn child or cause problems at delivery.

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

Fertility

No data available

Driving and using machines

No data available

3. HOW TO TAKE ANADIN TABLETS

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

Always take **ANADIN TABLETS** exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

ADULTS:

Take two tablets with water and repeat every six hours, if necessary (do not take more than 8 tablets within any 24-hour period).

CHILDREN:

Do not give to children under 12 years of age and consult a medical doctor before giving to children between the ages of 12 and 16 years.

If you take more ANADIN TABLETS than you should

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

Take any remaining tablets with you to show the doctor

If you forget to take ANADIN TABLETS

Do not double the dose. Continue taking ANADIN tablets as directed.

Contact your healthcare professional for further advice.

4. POSSIBLE SIDE EFFECTS

ANADIN tablets have side effects.

Not all side effects reported for ANADIN Tablets are included in this leaflet. Should your general health worsens or if you experience any untoward effects while taking ANADIN TABLETS please consult your medical doctor or pharmacist or other health care provider for advice.

If you experience any of these effects, then stop taking ANADIN tablets immediately and contact your doctor or pharmacist:

Stomach ulceration or perforation: Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces

- (stools/motions) or passing black stools.
- Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features.
- Breathing problems: Wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma.

Other possible side effects:

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

- Occasionally, the blood does not clot well which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- High caffeine intake can result in tremor (shaking) and palpitations (uncomfortable feeling in the chest caused by fluttering heartbeat). Aspirin may trigger gout in people prone to it.

- Other side effects include indigestion, heartburn, feeling of being sick, changes in skin colour, shortness of breath and a runny nose.

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

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

5. HOW TO STORE ANADIN TABLETS

Store in a cool dry place at or below 25 °C. Protect from light.

Keep the securitainer tightly closed.

Store in the original container.

Do not use after the expiry date shown on the carton, securitainer or sachet.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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

The active substance in ANADIN TABLETS is aspirin and caffeine.

Each tablet contains 400,0 mg of the active ingredient aspirin and 22,7 mg of the active ingredient caffeine.

The other ingredient: maize starch

What ANADIN TABLETS looks like and contents of the pack

Uncoated tablet

A white, biconvex tablet with the Anadin shield (a distinctive arrow) on each side.

The tablets are available in:

- paper sachets containing 2 tablets,
- white securitainers containing 50 or 100 tablets,
- clear PVC/silver aluminium foil blistered tablets packed in cartons containing 10 or 20 tablets.

Holder of Certificate of Registration

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