Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Disprin Melts
Dosage: Tablets
Strength: 300 mg aspirin
PIL Safety Update Approval: 06 Feb 2024

SCHEDULING STATUS: S0

DISPRIN MELTS 300 mg Tablets

Aspirin

Sugar free

Contains sweetener:

Saccharin 1.0 mg per tablet

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

DISPRIN MELTS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DISPRIN MELTS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DISPRIN MELTS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet:

1. What DISPRIN MELTS is and what it is used for

2. What you need to know before you take DISPRIN MELTS

3. How to take DISPRIN MELTS

4. Possible side effects

5. How to store DISPRIN MELTS

6. Contents of the pack and other information

1. What DISPRIN MELTS is and what it is used for

DISPRIN MELTS belong to a group of medicines which have analgesic (pain relieving), anti-pyretic (fever reducing) and anti-inflammatory (inflammation reducing) properties.

DISPRIN MELTS is used for the relief of mild to moderate pain and/or fever.

2. What you need to know before you take DISPRIN MELTS

Do not take DISPRIN MELTS or give to your child:

- if you or your child is hypersensitive (allergic) to Aspirin or any of the other ingredients of DISPRIN MELTS (listed in section 6)
- If you or your child is hypersensitive to other non-steroidal anti-inflammatory medicines.
- If you are pregnant of breastfeeding your baby (See **Pregnancy, breastfeeding and fertility**)
- If you or your child has Asthma – DISPRIN MELTS may cause allergic reactions in asthmatics
- A history of peptic ulcers, a blood or bleeding disorder
- If you or your child has haemophilia
- If you or your child has liver disease
- If you or your child has kidney disease
- If you or your child has heart failure
- If you or your child has dehydration
- If you or your child has anaemia
- If you or your child is receiving oral therapy to prevent blood clots such as warfarin.
- If you or your child has a history of gastrointestinal disease/complications.
- If your child is under 16 years of age.
- If you are over 60, only use DISPRIN MELTS after consulting your doctor

Warnings and precautions:

Take special care with DISPRIN MELTS if you have the following:

- stomach problems
- above 65 years of age (the elderly)
- SLE and mixed connective tissue disease
- skin conditions

- a history of hypertension or fluid retention
- asthma or allergic disease
- liver problems
- kidney problems
- gout
- if you are planning on becoming pregnant.
- if you are receiving medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin.

If you are undergoing surgery, stop taking DISPRIN MELTS several days before.

You need to discontinue DISPRIN MELTS treatment and consult your doctor if these occur during treatment:

- Drug reaction with eosinophilia and systemic symptoms (DRESS): a life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abdominal heartbeat.
- Serious skin reactions including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis: these are indicated by severe skin peeling, painful blisters and starts by flu-like illness.

Children and adolescents

There is an association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason, aspirin should not be given to children aged under 16 years.

Other medicines and DISPRIN MELTS:

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

DISPRIN MELTS should NOT be used together with:

Corticosteroids: steroid hormones used for severe allergies and skin problems.

Anti-platelet agents: Medications are used to prevent blood clots from forming e.g aspirin or clopidogrel

Antidepressants: used in the treatment of mood disorders

Calcium channel blockers: are used mainly in the management of chest pains, high blood pressure and irregular heartbeat.

Cardiac glycosides: These are medicines for treating heart failure and certain irregular heartbeats e.g digoxin.

Varicella vaccine: Chicken pox vaccine

Antihypertensives (ACE inhibitors and Angiotensin II Antagonists) and diuretics: Water tablets and other high blood pressure medicines.

Anti-coagulants: Medicines used for prevention of blood clots, e.g warfarin.

Other NSAIDs painkillers like ibuprofen and those used in the treatment of arthritis

Zidovudine: is used in the treatment of HIV infection and AIDS.

Metoclopramide & domperidone: are used for nausea and/or vomiting disorders.

Valproate: is used in the treatment of seizures (fits).

Uricosurics: used to treat gout

Quinoline antibiotics: Antibiotics for treating bacterial infections, e.g pneumonia and urinary infections)

Mifepristone: used to end pregnancy

Methotrexate: used in the treatment of cancer

Antidiabetics, sulphonylureas: diabetes (high blood sugar) medicines like insulin

When going for any blood or urine tests, always tell your healthcare professional if you are taking DISPRIN MELTS.

Other medicines may increase side effects of DISPRIN MELTS as well as mask symptoms of an overdose. Other medicines may increase gastrointestinal bleeding when taken with DISPRIN MELTS. DISPRIN MELTS may reduce the effects of other medicines if taken together and vice versa. DISPRIN MELTS may also interfere with thyroid and urine glucose tests.

DISPRIN MELTS with food and alcohol:

Taking DISPRIN MELTS with alcohol can damage the stomach and intestine lining.

Pregnancy, breastfeeding and fertility:

Do not take DISPRIN MELTS during pregnancy and while breastfeeding your infant.

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: The use of DISPRIN MELTS may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

Driving and using machines:

DISPRIN MELTS has very little to no influence on ability to drive and use machines.

It is not always possible to predict to what extend DISPRIN MELTS may interfere with the daily activities of a patient. Patients should ensure that thy do not engage in the above activities until they are aware of the measure to which DISPRIN MELTS affects them.

3. How to take DISPRIN MELTS

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

Always take DISPRIN MELTS exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

You should check with your doctor or pharmacist or nurse if you are not sure.

Adults: 1 to 3 tablets. Repeat 4 hourly if necessary but not more than 12 tablets to be taken during any 24 hour period.

Children 16 years and over: 1 to 3 not more than four times a day to a maximum of 10 tablets in 24 hours.

Do not give to children aged under 16 years, unless specifically told to by your doctor

Do not take more than 12 tablets in a 24 hour period

Warning: Do not use continuously for more than 10 days without consulting your doctor

If you take more DISPRIN MELTS 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.

The following symptoms will indicate a possible overdose:

- vomiting
- dehydration
- ringing in the ears
- dizziness
- deafness
- sweating
- warm arms and legs with bounding pulses
- increased respiratory rate
- hyperventilation.

If you take more DISPRIN MELTS than you should

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

If you forget to take DISPRIN MELTS tablets:

If you miss a dose of DISPRIN MELTS, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DISPRIN MELTS can have side effects.

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

If any of the following happens, stop taking DISPRIN MELTS

- increased risk of bleeding
- slow blood clotting
- bone marrow failure
- reduced number of blood cells
- fever
- skin rash
- severe itching of the skin
- swelling of the skin
- DRESS reaction (rash, facial swelling accompanied by abnormal heart rates)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DISPRIN MELTS.

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:

- increased blood level of sodium
- fluid retention
- stiff neck, sensitivity to light, headache caused by inflammation (swelling and redness) of the linings of the brain

- heart failure
- excess of watery fluid collecting in the cavities or tissues of the body
- high blood pressure
- narrowing of the small airways of the lungs that can cause wheezing and shortness of breath
- asthma
- shortness of breath
- hay fever
- bleeding in the digestive tract
- disturbances in the digestive tract
- sore (ulcer) in the lining of the stomach
- dark sticky faeces containing partly digested blood
- vomiting of blood
- sore (ulcer) in the lining of the mouth.
- cell death causing the epidermis (outer layer) to separate from the dermis (inner layer)
- increase in blood uric acid

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: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DISPRIN MELTS

5. How to store DISPRIN MELTS

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place

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 DISPRIN MELTS contains

The active substance is: Aspirin 300 mg

The other ingredients are: Glycine, lemon flavour, maize starch, microcrystalline cellulose, purified talc and saccharin.

What DISPRIN MELTS looks like and contents of the pack:

White, circular, flat, bevelled edges tablet with matt finish and a sword imprinted on one side and plain on the other side.

Round white tablets in packs of 8 and 32 tablets in foil.

Holder of Certificate of Registration

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

This leaflet was last revised in

Date on the registration certificate of Disprin Melts: 15/05/1984

Date of the most recently revised package insert as approved by council: 06/02/2024

Registration

R/2.8/99

Access to the corresponding Professional Information

To be made available electronically at: https://cpdcentre.co.za/rb-product-inserts/