PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

BESEMAX Tablets

Each tablet contains:

Paracetamol 450 mg

Orphenadrine 35 mg

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share BESEMAX 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 BESEMAX is and what it is used for
2. What you need to know before you take BESEMAX
3. How to take BESEMAX
4. Possible side effects
5. How to store BESEMAX
6. Contents of the pack and other information

1. What BESEMAX is and what it is used for

BESEMAX contains paracetamol 450 mg and orphenadrine 35 mg, which belongs to a group of medicine referred to Analgesic combinations.

BESEMAX is used for generalised pain and the relief of muscle spasm associated with acute painful musculo-skeletal conditions.

2. What you need to know before you take BESEMAX

Do not take BESEMAX:

If you are hypersensitive (allergic) to paracetamol and/or orphenadrine or any of the other ingredients of BESEMAX (listed in section 6)

If you suffer from the following:

- severe liver function impairment
- enlarged prostate
- achalasia (a failure of smooth muscle fibres to relax, which can cause the lower oesophageal sphincter to remain closed)
- bladder neck obstruction
- glaucoma (a condition in which the pressure of fluid in the eye is high. This can damage your eye's optic nerve)
- myasthenia gravis (a disorder causing extreme muscle weakness and can impact a person's ability to see, smile, walk, talk and breathe)
- peptic ulcer (a lesion in the lining (mucosa) of the digestive tract, typically in the stomach or duodenum)
- stenosing and pyloric or duodenal obstruction
- porphyria (a group of diseases in which substances called porphyrins build up, negatively affecting the skin or nervous system)
- If you are pregnant or breast-feeding

Warnings and precautions

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Special care should be taken with BESEMAX:

- If you suffer from liver or kidney disease
- If you are taking other central nervous system depression-producing medication as well as patients on anticholinergics or medication with anticholinergic properties.
- If you suffer from porphyria
- Use with caution in patients with cardiac disease
- Dosages in excess of those recommended may cause severe liver damage
- Do not use continuously for more than 10 days without consulting your doctor.

Use in children and adolescents

The use of Besemax in children and adolescents has not been established.

Other medicines and BESEMAX

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

Orphenadrine may increase central nervous system depression if taken concurrently with alcohol or central nervous system depressants. Anticholinergic effects may be intensified if orphenadrine is taken concurrently with anticholinergics or medication with anticholinergic effects.

Use of paracetamol with anticoagulants (medicines used to prevent blood clots) coumarin-or indandione-derivative may increase their effects.

Prolonged use of paracetamol and a salicylate significantly increases the risk of kidney damage.

Sleeping medication taken together with paracetamol decreases the therapeutic effect of paracetamol

Risk of hepatotoxicity with single toxic doses or prolonged use of high doses of paracetamol may be increased in alcoholics or in patients taking other hepatotoxic medications or hepatic enzyme inducers.

BESEMAX with food and drink

No known interactions with food and drink.

Pregnancy, breast-feeding and fertility

The safety of using BESEMAX during pregnancy, fertility and breastfeeding has not been established.

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.

Driving and using machines

This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

3. How to take BESEMAX

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

Always take BESEMAX exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are unsure.

Adults: Take 2 tablets, orally, 3 times a day.
DO NOT EXCEED THE RECOMMENDED DOSAGE.

If you take more BESEMAX than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
The most likely symptoms of overdosage are stomach pain and nausea, vomiting and insomnia.

If you forget to take BESEMAX
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
BESEMAX can have side effects:
Not all side effects reported for BESEMAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BESEMAX, please consult your health care provider for advice.
If any of the following happens, stop taking BESEMAX and tell your doctor immediately or go to the casualty department at your nearest hospital.

Side effects include:
Blood disorders:
Thrombocytopenia (decreased number of blood platelets), leucopenia (decreased number of white blood cells), pancytopenia (decreased number of cell elements in the blood), neutropenia (decreased number of neutrophilic leukocytes cells in the blood), agranulocytosis (low number of granulocytes, a type of white blood cell) and anaemia (low number of red blood cells).

Stomach and bowel disorders:
Pancreatitis (inflammation of the pancreas). Dryness of the mouth with difficulty in swallowing and talking, thirst, constipation and occasionally vomiting.

Skin disorders:
Skin rashes, dryness of the skin and other allergic reactions.

Liver disorders:
Hepatitis (inflammation of the liver)

Kidney disorders:
Renal colic (pain caused by a urinary tract stone), renal failure and sterile pyuria (urine which contains white blood cells) and difficulty in urination.

Eye disorders:
Dilation of the pupils with loss of accommodation and photophobia (extreme sensitivity to light).

Heart disorders:
Transient bradycardia (slowing of the heart beat) followed by tachycardia (fast heart beat) with palpitations and arrhythmias (abnormal rhythm of the heart).

Lung disorders:
Reduced bronchial secretion.

Nervous system disorders:
Confusion, dizziness and walking unsteadily.
Blood vessels disorders:
Flushing (sudden increase in blood flow).

Psychiatric disorders:
Insomnia (inability to sleep).

If you notice any side effects not mentioned in this leaflet, please inform your doctor of 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 "**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 BESEMAX.

May also report to Adcock Ingram Limited using the following email:
Adcock.AEReports@adcock.com

5. How to store BESEMAX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Protect from light.

Store in the original container

Keep the container tightly closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/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 Besemax contains:

BESEMAX contains the active ingredients paracetamol and orphenadrine.

Each Tablet contains:

450 mg of paracetamol and 35 mg of orphenadrine.

The other ingredients are:

Colloidal anhydrous silica, hydroxypropylmethylcellulose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycollate and stearic acid.

Sugar free.

What BESEMAX looks like and contents of the pack:

White, circular, biconvex tablets with a breakbar on one face.

20,40 and 120 tablets packed in PVC/aluminium foil blister packs.

50 and 100 tablets packed in white polypropylene securitainers with white low-density polyethylene (LDPE) closures.

120 tablets packed in white high-density polyethylene (HDPE) containers with white LDPE closure or white HDPE screw-on closures.

Holder of Certificate of Registration

Adcock Ingram Limited

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Customer Care: 0860 ADCOCK/232625

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Access to the corresponding professional information

It is contained in the packaging of the medicine

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