

BROMAZANIL 3 & 6 TABLET

Bromazepam

Patient Information Leaflet

BROMAZANIL 3 TABLET

Bromazepam 3mg

BROMAZANIL 6 TABLET

Bromazepam 6mg

Read this entire leaflet before you start taking the medication.

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT IS IN THIS LEAFLET?

1. What Bromazepam is used for
2. How Bromazepam works
3. Before you take Bromazepam
4. How to take Bromazepam
5. While you are using Bromazepam
6. Possible side effects
7. How to store Bromazepam
8. Product description
9. Marketing authorization holder and manufacturer

1. WHAT BROMAZANIL IS USED FOR

Bromazepam is used for anxiety, tension or agitation. Anxiety or tension associated with the normal stress of everyday life usually do not require any medication treatment.

Your doctor may have prescribed Bromazepam for another purpose.

2. HOW BROMAZANIL WORKS

Bromazepam contains bromazepam as the active ingredients.

Bromazepam belongs to the group of medicines called benzodiazepines. It works

by its action on the brain chemicals.

3. BEFORE YOU TAKE BROMAZANIL

When you must not take it

Do not take Bromazepam if you:

- Have ever had allergic reaction to bromazepam, the active ingredient, other medicines from benzodiazepine group or to any other ingredients in listed at the end of this leaflet,
- Have ever had a reaction which included swelling of the hands, lips, face or tongue with unknown causes,

If you are not sure whether you should start taking this medicine, consult your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Are pregnant or plan to become pregnant,
- Are breastfeeding or plan to breast feed,
- Have any kidney or liver problems,
- Have been given other medicines to treat high blood pressure,
- Have a family history of swelling of the face, lips, tongue, throat, hands or feet.

Taking / using other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Bromazepam may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Any other medicines for treatment of mental conditions,
- Sleeping pills,
- Narcotics (e.g. pethidine, morphine), used during surgery or for pain relief,
- Medicines for allergy or cold,
- Muscle relaxants,

- Pain relievers,
- Medicines for ulcer treatment (e.g. cimetidine),
- Cisapride, used for heartburn treatment,
- Any medicines for high blood pressure or other heart conditions,
- Medicines for heart failure (e.g. digoxin),
- Medicines to prevent blood clot formation (e.g. warfarin),
- Oral contraceptive pills,
- Theophylline, used for asthma,
- Alcohol

Other medicine not listed above may also interact with bromazepam. Your pharmacist or doctor will have more information on the medicines you should avoid.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Bromazepam is not recommended to be taken during pregnancy as it may cause harm to your baby.

Bromazepam passes into breast milk and there is possibility your baby may be affected. Bromazepam is not recommended to be taken while breast feeding.

4. HOW TO TAKE BROMAZANIL

Always take Bromazepam exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

How much to take

The dose given by your doctor may differ from this leaflet.

Usual Dosage:

Bromazepam is usually given at dose between 3 – 18mg daily given in divided dose. Depending on age and health condition, other dosage may be given. Elderly patients may require a lower dose.

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When to take it

Take the tablets according to your doctor's instruction.

Taking with food and drink

Bromazepam can be taken before or after meal. Swallow the tablet with a glass of water.

How long to take it

Do not take Bromazepam for longer than your doctor directed. Bromazepam is usually used for short periods only (e.g. 1-2 weeks). Continuous long-term use is not recommended unless advised by your doctor.

Prolonged continuous use of benzodiazepines may lead to dependence on the medicine.

If you forget to take it

Take your dose as soon as you remember and continue to take it as you would normally. If it is time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include drowsiness, confusion, slow reaction, slow heart beat, shortness of breath, problems in speech, difficulty in controlling muscles movement and walking unsteadily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. WHILE YOU ARE USING BROMAZANIL

Things you must do

- Always follow your doctor's instruction carefully.
- If you become pregnant while taking Bromazepam, tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Bromazepam.
- Inform any other doctors, dentists and pharmacists who treat you that you are taking Bromazepam.
- Visit your doctor regularly so that your progress can be checked.

Things you must not do

- Do not stop taking or change the dose of Bromazepam without your doctor's permission.
- Do not take Bromazepam to treat any other complaint unless your doctor tells you to.
- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not take Bromazepam for a longer time than your doctor has prescribed.
- Do not drive or operate machinery while you are taking Bromazepam. Bromazepam may cause dizziness or drowsiness in some people. Even if you take Bromazepam at night, you may still be dizzy or drowsy the next day.

Things to be careful of

- Be careful when drinking alcohol while you are taking Bromazepam. Combining alcohol and Bromazepam may worsen the dizziness, drowsiness or fainting. Avoid or reduce the amount of alcohol intake while you are taking Bromazepam.

6. POSSIBLE SIDE EFFECTS

All medicines can have side effects. Bromazepam may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects and they worry you:

- Dizziness,
- Tiredness,
- Mild reduction in blood pressure,
- Confusion,
- Headache,
- Unsteady movement,
- Dependence,
- Aggressive behavior,
- Hangover effects such as lack of concentration, and daytime sleepiness,
- Gastrointestinal disturbances,
- Changes in salivation,
- Blurred vision
- Inability to control bladder (incontinence)
- Difficulty in passing urine,
- Change in libido,
- Rashes,
- Blood disorders
- Jaundice,
- Short-term memory loss

Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.

7. HOW TO STORE BROMAZANIL

Store in between 15°C and 30°C. Store in original package to protect from heat, moisture, and light.

Do not store Bromazepam or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

Disposal

Do not use Bromazepam after the expiry date which is stated on the carton and blister. If your doctors tell you to stop taking Bromazepam or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

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8. PRODUCT DESCRIPTION

What Bromazepam looks like and contents of the pack.

Bromazepam 3 Tablet: White, oblong, biconvex tablets, three scores on each tablet face.

Bromazepam 6 Tablet: Green, oblong, biconvex tablets, three scores on each tablet face.

Packing

Bromazepam 3 and 6 Tablet is available in blister strip in a box of 10, 20 and 50 tablets.

What Bromazepam contains

The active ingredient is:

Bromazepam 3 Tablet – each tablet contains 3mg of Bromazepam.

Bromazepam 6 Tablet – each tablet contains 6mg of Bromazepam.

The other ingredients are:

Anhydrous colloidal silica, lactose, povidone, magnesium stearate and crospovidone.

Bromazepam 6 Tablet also contains green lake as colouring agent.

Registration Number

Bromazepam 3 Tablet: MAL20001548AC

Bromazepam 6 Tablet: MAL20001549AC

9. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Manufactured by:

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
D-39179 Barleben, Germany

For:

HEXAL AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

Marketing Authorisation Holder:

IMEKS Pharma Sdn. Bhd.
No. 1 & 2, Jalan 6/33B,
MWE Commercial Park,
52000 Kuala Lumpur. Malaysia

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