

BESQUIL TABLETS

Alprazolam (0.5 mg)

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What **BESQUIL TABLETS** is used for

BESQUIL TABLETS are used to treat anxiety and anxiety associated with depression.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

How **BESQUIL TABLETS** works

BESQUIL TABLETS contain alprazolam which belongs to one of a group of medicines called benzodiazepines.

Benzodiazepines like alprazolam affect chemical activity in the brain to promote sleep and to reduce anxiety and worry.

Before you use **BESQUIL TABLETS**

- When you must not use it

Do not take **BESQUIL TABLETS**

- if you have an allergy to alprazolam or any other medicine in the benzodiazepine group or any of the ingredients of **BESQUIL TABLETS** (see section Product description).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in

breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin

- You must not take **BESQUIL TABLETS** if you are taking medicines used to treat fungal infections such as ketoconazole and itraconazole.
- If you suffer from a disease called 'myasthenia gravis' where you suffer from very weak and tired muscles.
- If you have severe chest problems or breathing difficulties
- If you have severe liver problems
- If you have 'sleep apnoea' - this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.
- If you have increased pressure in the eye (acute narrow angle glaucoma)

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

The expiry date refers to the last day of that month. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether to start taking this medicine, talk to your doctor or pharmacist.

- Before you start to use it

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

You must tell your doctor if:

- you have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs. Your doctor may want to give you special help when you need to stop taking these tablets.
- you have liver or kidney problems.

Tell your doctor if you are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding.

It may cause respiratory problems in new born and may affect your

developing baby if you take it during pregnancy.

Alprazolam passes into breast milk and there is a possibility that your baby may be affected, e.g. your baby may become drowsy or experience feeling of tiredness or lose weight.

Do not give this medicine to a child unless advised by the child's doctor.

The safety and effectiveness of Alprazolam in children have not been established.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by **BESQUIL TABLETS** or may affect how well **BESQUIL TABLETS** works. These include:

- medicines used to treat anxiety or depression or to help you sleep (e.g. nefazodone, fluvoxamine, fluoxetine, sertraline).
- cimetidine (for treating stomach ulcers).
- antipsychotic medicines used to treat mental illnesses like schizophrenia (a severe brain disorder in which people interpret reality abnormally).
- medicines to treat epilepsy (fits).
- antihistamines for relief of allergies.
- oral contraceptives (birth control pills).
- diltiazem (used for angina and high blood pressure).
- certain antibiotics (e.g. erythromycin, troleandomycin).
- ritonavir or other similar medicines used for treating HIV.
- sleeping tablets
- sedatives (medicines used to produce calmness) or tranquilisers
- medicines for treating fungal infections (e.g. ketoconazole, itraconazole or other azole).
- some strong pain killers (e.g. propoxyphene)

- anaesthetic drugs (drugs used to put you to sleep during an operation or surgery)

It is important not to drink any alcohol while you are taking alprazolam, as alcohol increases the effects of the medicine.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines. You may need different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use BESQUIL TABLETS

- How much to use

The dose of alprazolam may be different for each person. Your doctor will decide the right dose for you.

Adult

The usual recommended dose is one half to one tablet, three times daily.

In some cases your doctor may recommend you one to two tablets at bedtime.

If clinically required your doctor may increase your dose in small increments. Where the dose does need to be increased, it is usual to increase the night time dose first, before the daytime doses to make sure you are more alert during the day. If you start to get side effects your doctor may lower your dose.

Elderly

If you are an older patient or you have for example kidney, liver or breathing problems and you need a lower dose, your doctor will decide your dose as per your condition.

Children

This medicine should not be used in children.

Do not take your tablets with an alcoholic drink.

- When to use it

Take your tablets at about the same time each day.

Your doctor will tell you how many times a day you should take your medicine, but taking it at the same time each day will have the best effect. It will also help you remember to take it.

- How long to use it

Usually **BESQUIL TABLETS** should be used for short periods only (should not exceed eight to twelve weeks including tapering off process).

Continuous long term use is not recommended unless advised by your doctor.

Continue taking alprazolam for as long as your doctor recommends and always see your doctor before you stop taking it.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

Do not take a double dose to make up for a missed dose.

- If you use too much (overdose)

It is important that you do not take more tablets than you are told to. If you do accidentally take too many tablets you may experience drowsiness, confusion, unsteadiness when walking, impaired coordination, diminished response to reflexes, drop in blood pressure, difficulty breathing and coma. If you do accidentally take too many tablets, seek medical attention straight away.

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much BESQUIL TABLETS.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers of these facilities handy.

While you are using BESQUIL TABLETS

- Things you must do

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

Take BESQUIL TABLETS exactly as your doctor has prescribed.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BESQUIL TABLETS.

Tell all doctors, dentists and pharmacists who are treating you that you are taking BESQUIL TABLETS.

If you are going to have an operation, tell your doctor or anaesthetist that you are taking BESQUIL TABLETS.

It may affect other medicines used during surgery.

If you become pregnant while you are taking this medicine, tell your doctor.

Tell your doctor if, for any reason, you have not taken BESQUIL TABLETS exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that BESQUIL TABLETS is not helping your condition, or appears to have stopped helping your condition.

Your doctor needs to check your progress and see whether you need to keep taking **BESQUIL TABLETS**. **Always discuss with your doctor any problems or difficulties during or after taking BESQUIL TABLETS. If you are being treated for anxiety, be**

sure to tell your doctor how you feel, especially if your anxiety attacks are getting worse or more frequent.

After taking **BESQUIL TABLETS** you may experience:

- sleep driving or making phone calls, preparing and eating food while asleep.
- memory loss.
- serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.

Tell your doctor if you experience any of the above.

- Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use BESQUIL TABLETS to treat any other complaints unless your doctor tells you to.

Do not take your medicine for a longer time than your doctor has prescribed (see subsection How long to use it).

Do not increase your dose of BESQUIL TABLETS, without first checking with your doctor.

If your symptoms have returned even though you are taking the same dose, you should speak to your doctor, who will determine whether a dose adjustment is required.

Do not stop taking BESQUIL TABLETS or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects (see "Withdrawal symptoms" in section Side Effects). You and your doctor will slowly reduce your dose of **BESQUIL TABLETS** before you can stop taking it completely.

- Things to be careful of

Be careful while driving or operating machinery until you know how BESQUIL TABLETS affect you.

Alprazolam may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to alprazolam before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

If you drink alcohol, symptoms such as sleepiness, dizziness or lightheadedness may be worse.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking **BESQUIL TABLETS**.

Be careful if you are elderly, unwell or taking other medicines.

You may be more likely to experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side Effects

Like other medicines, BESQUIL TABLETS may cause some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Serious side effects

If any of the following happens, Stop taking BESQUIL TABLETS and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

Tell your doctor as soon as possible if you notice any of the following

- loss of control of your bladder or bowels, difficulty passing urine

- uncontrollable muscle spasms affecting the eyes, head, neck and body
- tremor (shakiness)

Other side effects

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness, light-headedness, numbed emotions, reduced alertness, confusion, slurred speech, depression, loss of memory, sleeplessness, nervousness, tiredness, headache, dizziness,
- double or blurred vision, pressure in the eye
- gastrointestinal disturbances
- muscle weakness, unsteadiness when walking, musculoskeletal weakness
- skin reactions
- yellowing of the skin and whites of the eyes
- change in weight, loss of appetite,
- changes in libido, menstrual irregularities

Dependence and withdrawal symptoms

- It is possible to become dependent on medicines like **BESQUIL TABLETS** while you are taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment.
- Withdrawal symptoms are more common if you:
 - stop treatment suddenly
 - have been taking high doses
 - have been taking this medicine for long time
 - have a history of alcohol or drug abuse.

This can cause effects such as headaches, muscle pain, abdominal and muscle cramps, extreme anxiety, vomiting, sweating, tension, restlessness, confusion, mood changes, difficulty sleeping and irritability.

In severe cases of withdrawal you can also get the following symptoms: a feeling of unreality or detachment, the world may feel unreal, changes in hearing, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands, hallucinations (seeing or hearing things which are not there while you are awake), tremor or epileptic fits.

Laboratory Tests

- abnormally high levels of prolactin in the blood
- abnormal liver function tests

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of BESQUIL TABLETS

- Storage

Store below 30°C, protect from moisture

Keep BESQUIL TABLETS where children cannot reach it.

- Disposal

If your doctor tells you to stop taking **BESQUIL TABLETS**, or the tablets have passed their expiry date, ask your doctor what to do with any left over.

Product Description

- What BESQUIL TABLETS looks like

Peach colored, circular, biconvex tablets having scoreline on one side.

- Ingredients

- Active ingredient: Alprazolam
- Inactive ingredients: Lactose Monohydrate, Microcrystalline Cellulose (Avicel PH 101), Purified Water, Sunset Yellow Supra, Docusate Sodium and Sodium Benzoate, Maize Starch, Colloidal Anhydrous Silica and Magnesium Stearate

- MAL number:

MAL07122820A

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, Malaysia.

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