

**ANXYL®**  
**3 mg tablets**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about ANXYL**

Each tablet of ANXYL contains 3 mg Bromazepam.

Bromazepam is a benzodiazepine with anxiolytic and sedative effects; it is used for the relief of symptoms of anxiety. At high doses, bromazepam has sedative and muscle-relaxant properties.

ANXYL is indicated for the treatment of anxiety and tension states, depressive mood, nervous tension, agitation and insomnia.

It is also used to reduce anxiety and tension related to the functional disturbances of the cardiovascular, respiratory, circulatory, gastro-intestinal and genito-urinary systems or related to other psychosomatic disturbances

Your doctor may use this medicine to treat other conditions as well.

**The way to take ANXYL**

Take ANXYL as prescribed by your physician.

The recommended adult dose ranges from 1.5 mg (half a tablet) to 3 mg (1 tablet) up to 3 times per day; treatment should begin with low doses, gradually increasing to the optimum level. The dose must be adjusted individually on the basis of the response to treatment.

In severe cases and in psychiatry, higher doses may be needed: 6 mg to 12 mg 2 or 3 times per day.

Children, elderly and patients with renal dysfunction may take half the average daily dose.

ANXYL tablets may be taken before or with meals.

**Duration of treatment**

Do not take more of this medicine or take it longer than prescribed by our doctor.

The treatment must be as brief as possible. The indication must be regularly reevaluated, especially in the absence of symptoms. The global duration of treatment must not exceed 8 to 12 weeks for the majority of patients including the period of reduction of the dosage.

In some cases, it may be necessary to prolong the treatment but with periodic evaluation of the patient's state.

Do not discontinue the treatment without consulting your doctor.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

The specific antagonist of benzodiazepines is flumazenil.

**In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

**Contraindications**

This drug is contraindicated in case of:

- Hypersensitivity to benzodiazepines
- Severe respiratory insufficiency
- Syndrome of sleep apnea
- Severe hepatic insufficiency

**Precautions**

-The treatment must be progressively stopped, over a period of 2 weeks in case of prolonged use and/or high doses.

-Caution should be exercised when driving a car or operating dangerous machinery since drowsiness may occur.

-Caution with elderly, persons with renal or hepatic insufficiency and in addiction-prone patients.

-This drug may aggravate the symptoms of myasthenia.

-Pregnancy: this drug should not be used in the first trimester unless absolute necessity, and high doses should be avoided during the third trimester.

-This drug should not be used during lactation.

#### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Special precautions should be taken with drugs that cause drowsiness or relaxation.

It is not recommended to use with alcohol or drugs containing alcohol.

Use with precautions with other centrally active drugs such as neuroleptics, tranquilizers, anti-depressants, hypnotics, analgesics and anesthetics.

#### **Adverse reactions**

This drug is generally tolerated at therapeutic doses. Fatigue, drowsiness and rarely muscle weakness may occur with high doses; these symptoms regress on reduction of the dosage.

Some effects of benzodiazepines may change during a prolonged administration because of the tolerance development. This medicine can be habit-forming. A prolonged use and high doses may lead to physical and psychic pharmaco-dependence.

Abrupt discontinuation of the treatment may lead to withdrawal symptoms with a frequent insomnia, headache, important anxiety, myalgia, muscular tension and irritability and rarely agitation, convulsions and hallucinations.

Inform your doctor if any adverse reaction appears or becomes bothersome.

#### **Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

#### **Pack Presentation**

ANXYL, bromazepam 3 mg, pack of 20 tablets

**Revision date: 05/2005**

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