PRAZEPAM EG 10 mg tablets
PRAZEPAM EG 20 mg tablets
PRAZEPAM EG 15 mg/ml oral drops, solution

read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

what is in this leaflet
1. What Prazepam EG is and what it is used for
2. What you need to know before you take Prazepam EG
3. How to take Prazepam EG
4. Possible side effects
5. How to store Prazepam EG
6. Contents of the pack and other information

1. What Prazepam EG is and what it is used for

The active substance of Prazepam EG is prazepam. Prazepam is a benzodiazepine derivative and is indicated to treat symptoms of anxiety.

Benzodiazepines are used to treat severe incapacitating symptoms or symptoms leading to an extreme suffering for the patient.

Prazepam EG is used to treat anxiety and nervous tension requiring sedative treatment.

2. What you need to know before you take Prazepam EG

DO NOT take Prazepam EG:

- if you are allergic to prazepam or any of the other ingredients of this medicine (listed in section 6).
- if you have experienced an allergic reaction to other benzodiazepines in the past
- if you suffer from severe myasthenia (muscle weakness)
- if you have severe breathing difficulties
- in children below 6 years of age; use in children below 6 years of age is intended for rare and specific indications after evaluation and under the surveillance of a specialist (neuropaediatrician, psychiatrist)
- if you have sleep apnoea syndrome (when you stop breathing for a short time during your sleep)
- if you have severe hepatic insufficiency (severe liver disease)

Warnings and precautions

Talk to your doctor or pharmacist before taking Prazepam EG:

- Prazepam EG is only recommended for nervous disorders in which anxiety is a main feature. As a result, if you have severe mental illness, you should only be given prazepam as an additional ('add-on') treatment.
- if you are elderly or you are physically weakened, you may develop slight drowsiness and/or reduced mental sharpness in what you undertake as well as reduced muscle tone
- if you are elderly or severely weakened, you should start treatment at a dose of 10 or 15 mg prazepam (divided throughout the day), and increase this dose later on, if necessary.
• If you have non-specific, chronic breathing difficulties and dyspnoea (shortness of breath) your doctor should recommend a lower dose.

• The use of benzodiazepines in children below the age of 6 years is intended for rare and specific indications after evaluation and under the surveillance of a specialist (neuropaediatrician, psychiatrist) (See ‘DO NOT take Prazepam EG’). In children 6 to 18 years of age, dose reduction is recommended depending on the patient’s age and body weight. Children are more sensitive to the effects of the product on the central nervous system. Duration of treatment should be as short as possible.

• You should tell your doctor if you have a kidney or liver disorder (see section “Do not take Prazepam EG”).

• Benzodiazepines can lead to dependency. The risk of dependency increases with the dose and duration of treatment and in patients with a history of alcoholism or dependency on other substances. In this case, any abrupt discontinuation of treatment can lead to the withdrawal symptoms: headache, muscle pain, extreme anxiety, tension, confusion and irritability. In severe cases, the following symptoms may appear: derealisation (when things seem strange or unreal), depersonalisation (when you have an altered perception of yourself), hyperacusis (when you are unable to tolerate everyday sounds), numbness and tingling in the hands and feet (pins and needles), hypersensitivity to light, sound and physical contact, hallucinations (when you sense things that are not real), epileptic fits.

• Rebound anxiety: Stopping treatment may trigger a short-lasting syndrome, causing your original symptoms to re-occur in exaggerated form. Other reactions may occur, e.g. mood swings, anxiety, sleep disorders, convulsions, tremor, muscle and abdominal cramps, vomiting, sweating and agitation. The risk of withdrawal symptoms or rebound phenomenon is significantly increased if you suddenly stop your treatment, so your doctor will reduce your dose gradually.

• You may suffer from rebound anxiety when stopping Prazepam EG.

• You should take Prazepam EG for as short a time as possible, depending on your illness, and no longer than 8 - 12 weeks in case of anxiety, including the dose-reduction (“tapering-off”) phase. You should not take Prazepam EG for longer than this until your doctor has reassessed your condition.

• Benzodiazepines may lead to short-term memory loss, which usually occurs within a few hours after you have taken your medicine. As a consequence, in order to minimise this risk, patients need to be sure that they will have 7 to 8 hours of uninterrupted sleep following intake of the medicinal product.

• If you suffer from alcoholism or a dependency on other substances, you should take great care.

• If you are already taking other medicines, please also read the section “Taking other medicines”.

Other medicines and Prazepam EG
Prazepam EG should not be used together with other medicines that may decrease brain activity, e.g.:

• narcotics
• anaesthetics
• phenothiazines
• anticonvulsants
• sedative antihistamines
• barbiturates
• antidepressants
• antipsychotics (neuroleptic agents)
• monoamine oxidase inhibitors
• hypnotics
• anxiolytics/sedatives
• painkillers

Concomitant use of Prazepam EG and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Prazepam EG together with opioids the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Combined use of benzodiazepines and valproic acid increases the risk of psychosis (a loss of contact with reality).

Any combined use of benzodiazepines and clozapine should be carefully considered. In this case, your doctor may decide to reduce the benzodiazepine dose at the start of treatment.

The effect of Prazepam EG may be prolonged if used together with cimetidine or omeprazole (medicines used to treat ulcers).

The effect of Prazepam EG may be increased if used together with oral contraceptives (the Pill) and supplementary hormonal treatments, e.g. hormone replacement therapy (HRT).

Use of narcotic analgesics (e.g. morphine) can increase euphoria, resulting in increased psychological dependence (addiction).

Theophylline (an asthma medicine) works against the pharmacological effect of benzodiazepines.

Association of prazepam and buprenorphin is only possible after a careful benefit/risk evaluation. Contact your doctor before taking Prazepam EG.

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

**Prazepam EG with food, drink and alcohol**

Prazepam EG should not be used at the same time as other medicines which may decrease brain activity, including alcohol.

Do not drink any alcohol during treatment. The sedative effect of Prazepam EG can be increased by the consumption of alcohol during treatment, which may affect your ability to drive and use machines.

**Pregnancy and breast-feeding**

You should not take Prazepam EG if you are pregnant or you think you may be pregnant.

Inform your doctor if you become pregnant, or if you wish to become pregnant. In particular, Prazepam EG should not be taken in the first three months of pregnancy.

Prazepam should not be taken during childbirth.

Please tell your doctor if you are breast-feeding. If you are breast-feeding you should not take prazepam.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Depending on your individual sensitivity, the following side-effects may occur:

- drowsiness and/or reduced ability to concentrate
- amnesia (memory loss)
- a lack of concentration
- impaired muscle function
- reduced muscle tone
- slower reflexes.

Such effects can influence your ability to drive or use machines. If you are suffering from a lack of sleep you are at greater risk of reduced alertness. You should therefore be careful when driving vehicles or using dangerous tools, especially at the start of treatment.

**Prazepam EG tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
3. How to take Prazepam EG

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

All Prazepam EG formulations are intended for oral use. The amount of medicine to take (posology) will be decided by your doctor. The normal daily dose is between 10 and 60 mg of prazepam depending on the patient’s reaction.

**Adults**
Your doctor will decide on the daily dose that you should take. The recommended dose is 10-30 mg/day, depending on your response, and higher doses up to 60 mg should only be used for severe conditions.

**For elderly patients**
If you are elderly or severely weakened, you should start treatment at a dose of 10 or 15 mg prazepam (divided throughout the day), and increase this dose later on, if necessary.

**Use in children**
There are no clinical data on the use of Prazepam EG in children under 6 years of age. The use of Prazepam EG in children under 6 years of age should only be permitted after evaluation and under the surveillance of a specialist (neuropaediatrician, psychiatrist).

**For adolescents (12 to 17 years of age)**
Your dose will be decreased according to your age and body weight. The maximum dose of 1 mg per kg of body weight per day should not be exceeded. Your doctor will decide on the daily dose that you should take.

**Duration of treatment**
Your doctor will tell you how long you should go on taking Prazepam EG. In many cases, benzodiazepines need only be taken on an occasional or temporary basis, i.e. over a short period. Sometimes, your state of health requires the use of Prazepam EG over longer periods.

Whenever benzodiazepines are used over longer periods, your doctor will regularly assess if you need to continue treatment.

It is important to exercise caution when stopping treatment.

**Patients with liver or kidney disease**
Reduced doses must be considered for patients with impaired liver or kidney function.

**If you take more Prazepam EG than you should**
If you have taken more Prazepam EG than you should, or if a child has taken the medicine by accident, please contact your doctor or pharmacist or go to the nearest hospital immediately.

The visible signs of overdose are tiredness, sometimes with uncoordinated movements and confusion. As in all cases of overdose, the possibility of multiple drug involvement (i.e. that other drugs have also been taken) must be considered.

**If you forget to take Prazepam EG**
If you have forgotten your dose, take the next dose at your scheduled time. Do not take a double dose of Prazepam EG to make up for a forgotten dose.

**If you stop taking Prazepam EG**
Do not stop taking Prazepam EG suddenly under any circumstances, especially if you have been taking Prazepam EG for a long time. Symptoms may appear after suddenly stopping long-term benzodiazepine treatment (see “Take special care with Prazepam EG”). Always consult your doctor, who will explain how to reduce your dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. Possible side effects

Like all medicines, Prazepam EG can cause side effects, although not everybody gets them. Reported side-effects are summarised in the following table, by system and frequency. The frequencies are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

The following side effects have been identified with benzodiazepine use in general. They mainly occur at the start of treatment and mostly disappear as treatment continues.

**Blood and lymphatic system disorders:**
- Rare: Blood disorders (agranulocytosis).

**Cardiac disorders:**
- Common: Heart palpitations

**Eye disorders:**
- Common: Blurred vision, double vision

**Gastrointestinal disorders:**
- Common: Dry mouth, various gastrointestinal complaints

**General disorders and administration site conditions:**
- Common: Tiredness, weakness, altered libido, feeling drunk

**Hepatobiliary disorders:**
- Rare: Jaundice

**Investigations:**
- Rare: Bile output decreased

**Musculoskeletal and connective tissue disorders:**
- Common: Painful joints
- Uncommon: Swollen feet

**Nervous system disorders:**
- Very common: Somnolence
- Common: Drowsiness, dizziness, bouts of giddiness, uncoordinated movements, headache, trembling, problems of self-expression
- Uncommon: Fainting, altered state of consciousness, memory impairment (especially if you are elderly), epileptic fits, alertness decreased
- Not known: Falling (especially if you are elderly)

**Psychiatric disorders:**
- Common: Confusion, vivid dreams
- Uncommon: Agitation, irritability, increased insomnia, aggressiveness, increased anxiety, confusion
- Rare: Multiple personality, depression, psychosis, apathy or paradoxical reactions, delusion of persecution, paranoia

**Renal and urinary disorders:**
- Uncommon: Several genital and urinary disorders
Reproductive system and breast disorders:
Rare: Menstruation, ovulation and sexual disturbances
Very rare: Enlargement of breasts in males (gynaecomastia)

Respiratory, thoracic and mediastinal disorders:
Not known: Depressed breathing in patients with non-specific chronic respiratory disease.

Skin and subcutaneous tissue disorders:
Common: Severe bouts of sweating, temporary skin rash
Uncommon: Itching
Very rare: Hypersensitivity to foreign substances, anaphylactic shock

Amnesia:
Memory loss after taking Prazepam EG (anterograde amnesia) may occur at therapeutic doses. This risk increases with the dose. The effects of memory loss may be associated with inappropriate behaviour (see section “Take special care with Prazepam EG”).

Depression:
Hidden depression may become obvious during treatment with benzodiazepines.

Psychiatric and paradoxical reactions:
Reactions, such as:
- agitation
- irritability
- aggressiveness
- delirium (sudden lack of ability to focus your attention)
- bouts of rage
- nightmares
- hallucinations (sensing things that are not really there)
- psychoses (mental disorders)
- inappropriate behaviour and other behavioural problems
are known reactions during treatment with benzodiazepines or benzodiazepine-like products. Such reactions may also be relatively dangerous and are generally more common in the elderly.

Dependence:
Use of benzodiazepines (even at therapeutic doses) can lead to the development of physical dependence. As a result, stopping treatment might induce a withdrawal or rebound effect (see section “Warnings and precautions”). Psychological dependence may also develop. Cases of benzodiazepine abuse have been reported.

Prolonged use of benzodiazepines can cause physical and psychological dependence.

Symptoms that may present following abrupt withdrawal of prolonged benzodiazepine treatment include mood swings, (extreme) anxiety or sleeping disorders, agitation, convulsions, tremor, muscle and abdominal cramps, vomiting, sweating, headaches, muscle pain, tension, confusion and irritability. In severe cases, the following symptoms may present: derealisation, depersonalisation, hyperacusia, numbness and tingling in the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic fits; the risk of these symptoms appearing with prazepam is relatively small.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prazepam EG

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Drops: Prazepam EG 15 mg/ml oral drops, solution should be used within 30 days after first opening.

Do not use this medicine after the expiry date which is stated on the carton, blister or bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prazepam EG contains

- The active substance is prazepam.
  Each tablet contains 10 mg or 20 mg prazepam.
  1 ml of solution contains 15 mg prazepam (equivalent to 30 drops).

- The other ingredients are:
  Prazepam EG 10 mg tablets:
  - lactose monohydrate
  - microcrystalline cellulose
  - maize starch
  - magnesium stearate
  - indigotin Lake (E132)

  Prazepam EG 20 mg tablets:
  - lactose monohydrate
  - microcrystalline cellulose
  - maize starch
  - magnesium stearate
  - colloidal silica

  Prazepam EG 15 mg/ml oral drops, solution:
  - propylene glycol
  - diethylene glycol monoethyl ether
  - sodium saccharin
  - polysorbate 80
  - menthol
  - anethol
  - E 131 Patent blue V

What Prazepam EG looks like and contents of the pack

Prazepam EG 10 mg tablets are scored blue tablets and are available in Aluminium/PVC blister packs of 20, 30, 40, 50 and 60 tablets. The tablet can be divided into equal halves.

Prazepam EG 20 mg tablets are scored white tablets and are available in Aluminium/PVC blister packs of 20, 50 and 60 tablets. The tablet can be divided into equal halves.

Prazepam EG 15 mg/ml oral drops, solution is available in 20 ml dropper containers.
30 drops of the solution correspond with 1 ml and thus 15 mg prazepam.

Not all pack sizes may be marketed.
Marketing Authorisation Holder

<to be completed nationally>

Manufacturer

Prazepam EG 10 mg tablets:
Cosmo S.p.A.
Via C. Colombo, 1
20020 Lainate (MI)
Italy

Sanico NV
Veedijk 59
2300 Turnhout
Belgium

EG (Eurogenerics) NV
Heizel Esplanade b22
B-1020 Brussels
Belgium

Laboratoires BTT
Zone Industrielle de Krafft
67150 Erstein
France

Prazepam EG 20 mg tablets:
Cosmo S.p.A.
Via C. Colombo, 1
20020 Lainate (MI)
Italy

Sanico NV
Veedijk 59
2300 Turnhout
Belgium

EG (Eurogenerics) NV
Heizel Esplanade b22
B-1020 Brussels
Belgium

Laboratoires BTT
Zone Industrielle de Krafft
67150 Erstein
France

Prazepam EG drops
Cosmo S.p.A.Via C. Colombo, 1
20020 Lainate (MI)
Italy

Sanico NV
Veedijk 59
2300 Turnhout
Belgium

EG (Eurogenerics) NV
Heizel Esplanade b22
B-1020 Brussels
Belgium
This medicinal product is authorised in the Member States of the EEA under the following names:
< {Name of the Member State} > < {Name of the medicinal product}

This leaflet was last approved/revised in XX/2019 / 02/2019.