Clinical recommendation: 23.05.2019 (received 21.08.2019). Date submitted: 22.01.2020

Proposed patient information leaflet for URBANOL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

URBANOL® 5 mg CAPSULES

Clobazam

Contains sugar (lactose): 127 mg

URBANOL® 10 mg TABLETS

Clobazam

Contains sugar (lactose monohydrate): 72,3 mg

Read all of this leaflet carefully before you start taking URBANOL

- Keep this leaflet. You may need to read it again.
- If you have further quw2222estions, please ask your doctor or your pharmacist.
- URBANOL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

6. Contents of the pack and other information.

1. WHAT URBANOL IS AND WHAT IT IS USED FOR

URBANOL contains a medicine called clobazam. This belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain.

URBANOL can be used for:

- severe anxiety, over a short period of time
- relieving the short-term (acute) symptoms of alcohol withdrawal syndrome (effects experienced when a person stops consuming alcohol).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE URBANOL

Do not take URBANOL if:

- you are hypersensitive (allergic) to benzodiazepines, or clobazam or any of the other ingredients of URBANOL (listed in section 6)
- you have ever had problems with drugs or alcohol dependence in the past
- you have a long-term (chronic) condition in which the muscles become weak and tire easily (myasthenia gravis)
- you have serious breathing problems (severe respiratory insufficiency)
- you stop breathing for short periods during sleep (sleep apnoea syndrome)
- you have serious liver problems
- you are in the first three months of pregnancy or think you might be pregnant (see below, under PREGNANCY, BREASTFEEDING AND FERTILITY for more information)
- you are breastfeeding
- the patient or your child is 3 years old or younger.

Do not take URBANOL if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking URBANOL.

Warning and precautions

Take special care with URBANOL:

Check with your doctor or pharmacist before taking URBANOL:

- you should avoid drinking alcohol during treatment with URBANOL, as this could increase the risk of the side effects of URBANOL
- you may experience anterograde amnesia (loss of memory of events following trauma) if you are taking high doses of URBANOL
- if you have ever become dependent upon another drug or alcohol
- URBANOL can be addictive and cause withdrawal effects if treatment is stopped abruptly. Your doctor will prescribe URBANOL for a limited duration and decrease your dosage gradually to prevent these withdrawal effects from happening
- if you have shallow breathing (respiratory depression)
- if you have problems controlling your movements (spinal or cerebellar ataxia)
- if you have liver or kidney problems
- if you are an elderly person (the side effects of URBANOL may be stronger)
- if you have depression, irrational fears and obsessions
- if you have delusions (believing things which are not true) or hallucinations (sensing things which are not there).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking URBANOL.

Other medicines and URBANOL:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of URBANOL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

This is because URBANOL can affect the way some other medicines work. Some medicines can affect the way URBANOL works.

In particular, tell your doctor if you are taking any of the following:

- medicines for epilepsy (such as phenytoin, carbamazepine or valproic acid)
- medicines for depression (such as MAOIs (monoamine oxidase inhibitors) or tricyclic antidepressants (such as trazodone)
- medicines for severe mental illness called 'neuroleptics' (such as chlorpromazine, haloperidol and/or clozapine)
- painkillers (medicines containing e.g. codeine, dihydrocodeine or morphine)
- sleeping tablets (such as zolpidem)
- tranquillisers (such as diazepam or lorazepam)
- muscle relaxants (such as baclofen)
- antihistamines that make you sleepy (such as chlorpheniramine, promethazine or diphenhydramine)
- lithium - used for a mental illness called 'manic-depressive illness' (mood changes between a state of high excitability or exaggerated emotions and depression).

If you are not sure if any of the above apply to you talk to your doctor or pharmacist.

Anaesthetics:

If you are going to have an anaesthetic, tell your doctor or anaesthetist you are taking URBANOL. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

URBANOL with food, drink and alcohol:

- You should not use alcohol during treatment with URBANOL (see TAKE SPECIAL CARE WITH URBANOL)

- URBANOL can be taken with or without food.

Pregnancy, breastfeeding and fertility:

Do not take URBANOL if you are:

- in the first three months of pregnancy
- breastfeeding, since URBANOL passes into the breast milk.

Tell your doctor before taking URBANOL if you are pregnant, plan to get pregnant, or think you may be pregnant. This is because URBANOL is not recommended for use in pregnant women.

However, your doctor may give you URBANOL during late pregnancy or during labour.

- If this happens, there is a risk of having a baby with a low body temperature, floppiness, and breathing or feeding problems.

If URBANOL is taken regularly in late pregnancy, your baby may get withdrawal symptoms.

If you are pregnant or breastfeeding while taking URBANOL, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

You may feel sleepy or have concentration or memory problems after taking URBANOL. You may also experience double vision or you may react more slowly to things. If this happens, do not drive or use any tools or machines.

URBANOL 5 mg CAPSULES contains lactose and URBANOL 10 mg TABLETS contains lactose monohydrate:

If you have been told by your doctor that you cannot tolerate some sugars, tell your doctor before taking URBANOL. This is because URBANOL contains lactose.

3. HOW TO TAKE URBANOL

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

Always take URBANOL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with URBANOL will last. Do not stop treatment early or abruptly because you may experience serious side effects.

If you have the impression that the effect of URBANOL is too strong or too weak for you, tell your doctor or pharmacist.

Taking URBANOL:

- each capsule should be swallowed whole, and without chewing; with a glass of water
- URBANOL can be taken with or without food
- keep taking URBANOL until your doctor tells you to stop
- URBANOL is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should continue your treatment.

How much to take:

Adults:

- Your doctor will decide on the dose you should take.
- The usual dose is 10 mg to 30 mg each day. This can be taken as two separate doses or as a single dose at night.
- Your doctor may lower the dose to suit you.

Children (over 3 years old) and the elderly:

The daily dose will be half of the adult dose.

In people with kidney or liver problems:

The dosage will be determined by the prescribing doctor, as adjustments might be necessary.

If you take more URBANOL than you should:

If you take more URBANOL than you should or in the event of overdosage, tell your doctor/pharmacist or go to the casualty department at your nearest hospital straight away. Do not drive yourself, because you may start to feel sleepy. Remember to take the pack and any tablets that are left, with you. This is so the doctor knows what you have taken.

If you forget to take/miss a dose of URBANOL:

- If you miss a dose of URBANOL, take it as soon as you remember.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for any forgotten dose.

If you stop taking URBANOL:

Keep taking URBANOL until your doctor tells you to stop.

Do not stop taking URBANOL just because you feel better.

- When your doctor says you can stop taking URBANOL, you need to do this gradually. Your doctor will help you to do this.
- Stopping URBANOL can make you feel stressed (anxious), confused or depressed. You may also lose your appetite and have difficulty sleeping. Tell your doctor if this happens.

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

4. POSSIBLE SIDE EFFECTS

URBANOL can have side effects.

Not all side effects reported for URBANOL are included in this leaflet. Should your general health worsen while taking URBANOL, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking URBANOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing'
- 'rash or itching'
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to URBANOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- feeling restless, have difficulty sleeping or nightmares
- feeling irritable or anxious
- believing things which are not true (delusions)
- sensing things which are not there (hallucinations)
- feeling suicidal

These are all serious side effects. You may need urgent medical attention.

If you get any of the above side effects, your doctor may decide that your treatment needs to be stopped. These side effects are more likely to happen in elderly people and children.

Tell your doctor if you notice any of the following:

These side effects are more likely to happen at the start of treatment. They usually last for a short time. Tell your doctor or pharmacist if they get serious or last longer than a few days:

- feeling sleepy or dizzy
- dry mouth, constipation
- loss of appetite, feeling sick (nausea/vomiting)
- shaking fingers

Other side effects include:

- difficulty in staying awake or alert
- reacting to things more slowly than usual
- loss of memory, confusion
- headaches
- muscle weakness
- problems walking or other movement problems
- loss of sexual drive
- being aggressive
- depression of mood
- becoming dependent on URBANOL (physical or mental dependence)
- eye problems such as double vision
- breathing problems
- liver problems
- skin rashes (pinkish, itchy swellings called ‘hives’)
- Stevens-Johnson syndrome (rare skin condition with severe blisters and bleeding in lips, eyes, mouth, nose and genitals)

- toxic epidermal necrolysis (severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin, accompanied by fever, chills, aching muscles)
- weight gain
- increased risk of falling in the elderly
- blood dyscrasias (bleeding or bruising more easily than normal, nosebleeds, looking pale, fever, severe chills, sore throat or mouth ulcers).

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other healthcare professional.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel.).

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of URBANOL.

5. HOW TO STORE URBANOL

Store at or below 25°C, in a dry place.

Protect from moisture.

STORE ALLL MEDICINES OUT OF REACH OF CHILDREN.

Do not use URBANOL after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Return unused or expired medicines to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What URBANOL contains

URBANOL 5 mg CAPSULES:

Each capsule contains 5 mg clobazam as active ingredient.

The other ingredients are: Lactose, magnesium stearate, talc.

Capsule shell: gelatine, indigotin, titanium dioxide (E171).

URBANOL 10 mg TABLETS:

Each tablet contains 10 mg clobazam as active ingredient.

The other ingredients are: Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, talc.

What URBANOL looks like and contents of the pack

URBANOL 5 mg CAPSULES: opaque blue and white unprinted capsules (size no.4) containing a white powder.

URBANOL 10 mg TABLETS: white bi-planar round tablets scored and engraved with “CBZ” and “10” on one side, and plain on the other side.

URBANOL is available as 5 mg capsules and 10 mg tablets packed into opaque white PVC/acetochloride and aluminium blister packs, inserted into outer printed cardboard cartons, containing 100 capsules/tablets each (5x 20 blister packs).

HOLDER OF CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd.

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on the registration certificate (original registration):

URBANOL 5 mg CAPSULES : 8 November 1978

URBANOL 10 mg TABLETS : 20 July 1979

Date of most recently revised patient information leaflet as approved by Council:

To be allocated

REGISTRATION NUMBERS

URBANOL 5 mg CAPSULES : L/2.6/52

URBANOL 10 mg TABLETS : M/2.6/128