PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

RUSLOPAM 1 mg/mL

concentrate for solution for injection/infusion

Clonazepam

Sugar free

Read all of this leaflet carefully before RUSLOPAM is administered to you:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What RUSLOPAM is and what it is used for

RUSLOPAM contains clonazepam as the active substance, which belongs to a group of medicines known as benzodiazepines. Clonazepam has anticonvulsant properties, that is, it prevents seizures (fits). RUSLOPAM is used for the treatment of epilepsy in infants, children and adults. RUSLOPAM is used also for the treatment of panic disorder, with or without the fear of closed spaces.

2. What you need to know before RUSLOPAM is administered to you

RUSLOPAM should not be administered to you:

- If you are hypersensitive (allergic) to clonazepam or to any of the other ingredients of RUSLOPAM listed in section 6 of this leaflet.
- If you suffer from a serious lung disease.
- If you have an eye condition called acute narrow angle glaucoma, which causes intense eye pain.
- If you have a condition called myasthenia gravis (where your muscles become weak and your get tired easily).
- If you have a condition called sleep apnoea syndrome (where your breathing stops when you are asleep).

RUSLOPAM ampoules should not be used to treat newborn babies, especially those born prematurely.

Warnings and precautions

Take special care with RUSLOPAM:

- If you suffer from a form of incoordination of the muscles called spinal or cerebellar ataxia.
- If you are currently under the influence of alcohol.
- If you are taking other medicines used for epilepsy, medicines used to help you sleep, pain medicines, medicines used for depression, lithium or other medicines used to treat mood disorders.
- If you are an elderly person.
- If you have a lung, liver or kidney disorder.
- If you regularly drink alcohol or use recreational medicines.
- If you have a history of depression and/or suicide attempts.

RUSLOPAM must not be given if any of the above apply to you. If you are not sure, talk to your

doctor or nurse before receiving RUSLOPAM.

Dependence

Taking RUSLOPAM can lead to physical and psychological of dependence, which may increase with higher doses and longer duration of treatment. Patients with a history of alcohol and/or drug abuse have higher risk of becoming dependant on RUSLOPAM. Contact your doctor if you suspect you may be dependant on RUSLOPAM before treatment is stopped.

Other medicines and RUSLOPAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or nurse if you are taking any of the following medicines:

- Other medicines to treat epilepsy, such as carbamazepine, phenobarbital, phenytoin or sodium valproate.
- Medicines that cause anaesthesia (used during tests and surgical operations to numb sensation in certain areas of the body or induce sleep).
- Medicines used to make you sleep (hypnotics).
- Painkillers (analgesics).

RUSLOPAM with alcohol

You must not drink alcohol whilst taking RUSLOPAM as this may provoke epileptic seizures (fits).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before RUSLOPAM is administered to you.

RUSLOPAM should not be used if you are breastfeeding as it passed into the breast milk.

Driving and using machines

RUSLOPAM may affect your ability to drive or use machines. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This may be made worse if you consume alcohol. Take care if your doctor increases your dose or changes the frequency of when you receive RUSLOPAM, as this may also affect your ability to drive and use machines.

Propylene glycol

RUSLOPAM contains 802 mg propylene glycol in each 1 mL, which is equivalent to 80 % *m/v*.

Benzyl alcohol

RUSLOPAM contains 30 mg benzyl alcohol in each ampoule.

Benzyl alcohol may cause allergic reactions.

Ethanol

RUSLOPAM contains 159 mg of alcohol (ethanol) in each ampoule. The small amount of alcohol in RUSLOPAM will not have any noticeable effects.

3. How RUSLOPAM will be administered to you

You will not be expected to give yourself RUSLOPAM. It will be given to you by a person who is qualified to do so.

RUSLOPAM is usually administered by a doctor or nurse into a vein. It should always be used as directed by a doctor.

The normal adult dose is 1 mg (2 mL) by slow intravenous injection.

The normal dose in children is 0,5 mg (1 mL) by slow intravenous injection.

The dose given to the elderly will differ from the normal adult dose.

Alternatively, up to 3 mg may be given by intravenous infusion.

Your doctor will tell you how long your treatment with RUSLOPAM will last. If you have the impression that the effect of RUSLOPAM is too strong or too weak, tell your doctor or pharmacist.

If you are given more RUSLOPAM than you should

Benzodiazepines such as RUSLOPAM, commonly cause drowsiness, confusion, muscle weakness, difficulty speaking and involuntary eye movements.
Since a health care provider will administer RUSLOPAM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use RUSLOPAM

Since a health care provider will administer RUSLOPAM, it is unlikely that the dose will be missed.

If you stop using RUSLOPAM

If you receive long term treatment with RUSLOPAM (you are given the medicine for a long time) you may become dependent upon this medicine and get withdrawal symptoms. Sometimes withdrawal effects occur if the medicine is stopped suddenly and these may include sleep disturbances, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, irritability, sweating, shaking or trembling, headaches and agitation. In serious cases, withdrawal effects can also include being oversensitive to light, noise and physical contact, hallucinations, tingling and numbness and a feeling of being unreal. Treatment with RUSLOPAM must not be stopped suddenly. If this happens, your fits may return, and you may get withdrawal symptoms. If the dose of RUSLOPAM you are being given has to be reduced, or stopped, this must be done gradually.
Your doctor will explain how this will be done. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

RUSLOPAM can have side effects.

Not all side effects reported for RUSLOPAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while RUSLOPAM is administered, please consult your health care provider for advice.

If any of the following happens, stop using RUSLOPAM 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 RUSLOPAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections such as influenza (flu) or sinusitis
- feeling depressed
- lack of concentration
- difficulty sleeping
- feeling irritated
- abnormal coordination or loss of balance
- muscle weakness
- dizziness
- headache
- feeling light-headed
- drowsiness

- infections in the nose, throat or airways
- nausea
- tiredness.

Side effects where the frequency is unknown:

- low blood platelet counts
- restlessness, confusion and disorientation
- being excited, irritated, aggressive, agitated, nervous, hostile or anxious
- problems sleeping, nightmares and vivid dreams
- decrease in sexual drive (loss of libido)
- confusion, slowed reaction time
- in long-term or high-dose treatment, disorders such as a slowing or slurring of speech (dysarthria), reduced coordination of movements and gait (ataxia) and disorders of vision (double vision, nystagmus) may occur
- temporary memory loss
- double vision
- blood clots
- difficulty breathing
- stomach problems
- rash, itching, hives
- hair loss or changes in skin pigmentation
- muscle weakness
- loss of bladder control
- erectile disfunction in men (impotence)
- a higher risk of falling and breaking bones in elderly people.

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

Reporting of side effects:

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RUSLOPAM.

5. How to store RUSLOPAM

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Keep the ampoules in the outer carton to protect from light.
- Do not use after the expiry date printed on the carton or ampoule.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RUSLOPAM contains

The active substance is clonazepam.

Each 1 mL contains 1 mg clonazepam.

The other ingredients are 30 mg benzyl alcohol, 159 mg ethanol (99 %), 802 mg propylene glycol and glacial acetic acid.

What RUSLOPAM looks like and contents of the pack

A clear, colourless or slightly greenish yellow solution.

RUSLOPAM is available in a 1 mL amber NEG (USP type 1) glass ampoule with white OPC dot or a 1 mL amber fiolax (USP type 1) glass ampoule with yellow OPC dot.

Pack sizes: 1 or 10 ampoules.

Not all pack sizes may be marketed.

Holder of certificate of registration

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