PATIENT INFORMATION LEAFLET

BUSACAİN SPİNAL HEAVY 0,5% Ampoule Containing Solution for Injection

Sterile - Apyrogen

Administered into the spinal cord.

- ***Active substance:*** Each ampoule contains 5 mg of bupivacaine hydrochloride as drug substance in 1 mL solution.
- ***Excipients:*** Dextrose monohydrate, sodium hydroxide/hydrochloric acid, water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

What is in this leaflet:

Headings are included.

1. What BUSACAİN SPİNAL HEAVY is and what it is used for?

- BUSACAİN SPİNAL HEAVY is presented in packages containing 5 ampoules.
- BUSACAİN SPİNAL HEAVY contains 5 mg of bupivacaine hydrochloride in 1 mL of active ingredient in 4 mL of injection solution per ampoule. Clear, colorless solution for injection.
- BUSACAİN SPİNAL HEAVY belongs to a group of drugs called local anesthetics.
- BUSACAİN SPİNAL HEAVY is used to anesthetize certain parts of your body during surgery and during labor (anesthesia).

- BUSACAİN SPİNAL HEAVY is also used in operations related to the abdominal region of the body, the urinary tract system, the reproductive system of men and the lower part of the body.

2. What you need to know before you use BUSACAİN SPİNAL HEAVY

DO NOT USE BUSACAİN SPİNAL HEAVY for the following cases;

If;

- You are allergic to any of the excipients (see list of excipients) contained in the composition of bupivacaine or BUSACAİN SPİNAL HEAVY,
- You are allergic to other local anesthetic drugs (such as lidocaine or ropivacaine) in the medication group that includes BUSACAİN SPİNAL HEAVY,
- You have a skin infection (inflammation-causing microbial disease) near the site of injection,
- You have a disease that causes fever and tremor as a result of bacteria passing into the blood (septicemia),
- You have a condition called cardiogenic shock (a serious condition where the heart cannot provide enough blood to the body),
- You have a condition called hypovolemic shock (very low blood pressure, which causes a sudden collapse of the circulation [shock; collapse]),
- You have problems with your blood clotting,
- You have brain or spine diseases such as meningitis, polio (polio) or spondylitis (inflammation of the vertebrae or vertebrae),
- You have a severe headache caused by bleeding in your head (intracranial hemorrhage),
- You have problems in your spinal cord caused by anemia,
- You have recently been traumatized or have been diagnosed with tuberculosis or spine tumors

USE BUSACAİN SPİNAL HEAVY CAREFULLY for the following cases;

If;

- You have heart, liver or kidney problems (your doctor may need to adjust the dose for BUSACAİN SPİNAL HEAVY in these cases),
- You are told that you have reduced blood volume (hypovolemia),
- You have fluid in your lungs.
- If these warnings apply to you, even at any time in the past, or if you are unsure whether

they are valid, please consult your doctor before using BUSACAİN SPİNAL HEAVY.

Use of BUSACAİN SPİNAL HEAVY with food and drink

No interaction with food and drink with BUSACAİN SPİNAL HEAVY.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

If you are pregnant or think you may be pregnant, your doctor will not apply BUSACAİN SPİNAL HEAVY unless you consider it necessary.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Consult your physician before being given BUSACAİN SPİNAL HEAVY if you are breast-feeding**.**

Driving and using machines

BUSACAİN SPİNAL HEAVY can make you feel sleepy and may affect the speed of your reactions. For this reason, do not drive or use the machine until the next day after you were administered BUSACAİN SPİNAL HEAVY.

Important information about some excipients found in the composition of BUSACAİN SPİNAL HEAVY

BUSACAİN SPİNAL HEAVY contains less than 1 mmol (23 mg) of sodium per dose; in other words, it can be considered as “sodium-free”.

Use with other medicines

If;

- You use other local anesthetics,
- You use medications used to treat irregular heartbeat (arrhythmia), such as amiodarone, please inform your doctor as it may be necessary to adjust the dose of BUSACAİN SPİNAL HEAVY.

If you are using or have recently used any type of prescription or non-prescription drugs,

please inform your physician or your pharmacist.

3. How to use BUSACAİN SPİNAL HEAVY

Instructions for appropriate use and dose/administration frequency:

BUSACAİN SPİNAL HEAVY will be administered by your doctor. Your doctor will decide on the correct dose of BUSACAİN SPİNAL HEAVY.

Route and Method of administration:

BUSACAİN SPİNAL HEAVY will be administered to your spinal cord by injection from the lower part of your spine. BUSACAİN SPİNAL HEAVY prevents nerves from transmitting pain messages to the brain when it is injected.

Various age groups

Pediatric Use:

The safety and efficacy of BUSACAİN SPİNAL HEAVY in children has not been studied.

Geriatric Use:

The safety and efficacy of BUSACAİN SPİNAL HEAVY in the elderly have not been studied.

The dose of BUSACAİN SPİNAL HEAVY may need to be reduced in elderly patients.

Special use cases

Renal impairment:

Safety and efficacy of BUSACAİN SPİNAL HEAVY in patients with renal failure has not been studied. In these patients, it may be necessary to reduce the dose of BUSACAİN SPİNAL HEAVY.

Hepatic impairment:

Safety and efficacy of BUSACAİN SPİNAL HEAVY in patients with liver failure have not been studied. In these patients, it may be necessary to reduce the dose of BUSACAİN SPİNAL HEAVY.

Talk to your doctor or pharmacist if you have the impression that the effect of BUSACAİN SPİNAL HEAVY is too strong or weak.

If you have used more BUSACAİN SPİNAL HEAVY than you should

If you are given more BUSACAİN SPİNAL HEAVY than you should, occurred serious side effects will require special treatment.

The first signs of giving you more BUSACAİN SPİNAL HEAVY than you should usually do are:

- Lightheadedness or blackout,
- Lips and mouth contour,
- Language matching,
- Hearing problems.
- Problems related to vision (eye sight)

To reduce the risk of serious side effects, your doctor will stop giving you BUSACAİN SPİNAL HEAVY as soon as these symptoms appear. If you have any of the above symptoms or if you think you are using more than you should use from BUSACAİN SPİNAL HEAVY, talk to your physician immediately.

More serious side effects from giving you more BUSACAİN SPİNAL HEAVY include shaking, seizures and heart problems.

Talk to a doctor or pharmacist if you have used more than you should use from BUSACAİN SPİNAL HEAVY.

If you forget to use BUSACAİN SPİNAL HEAVY

Not possible.

Effects which may occur when treatment with BUSACAİN SPİNAL HEAVY is concluded

None.

If you have any further questions about the use of this medicine, ask your physician or pharmacist.

4. What are the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the ingredients of BUSACAİN SPİNAL HEAVY.

Side effects are listed in the following categories:

Very common	: It can be seen in at least 1 of 10 patients.
Common	: Less than one in 10 patients, but more than one in 100 patients.
Uncommon	: less than one in 100 patients, but more than one in 1.000 patients.

Rare	: Less than one in 1.000 patients, but more than one in 10.000 patients
Very rare	: less than one in 10.000 patients may be seen.
Unknown	: It cannot be estimated from the available data.

Stop using BUSACAİN SPİNAL HEAVY if any of the following occur, and immediately notify your physician or consult the emergency department of your nearest hospital:

Severe allergic reactions:

Symptoms may include the sudden onset of the following conditions:

- Swelling of the face, lips, tongue or throat. This may cause difficulty in swallowing.
- Severe or sudden swelling of hands, feet and wrists
- Difficulty in breathing
- Severe itching of the skin (with blisters)
- Very low blood pressure, which can cause fainting or shock.

These are all very serious side effects. If you have one of these is happen to you it means that you have a serious allergy to BUSACAİN SPİNAL HEAVY. You may need urgent medical attention or hospitalization.

All of these very serious side effects are rare (in one in 1000 patients).

Other side effects:

Nervous System Disorder

Common: Headache

Uncommon: Numbness (paresthesia), reduced voluntary movements in a particular muscle group (paresis), impaired sense of touch and pain (dysesthesia)

Rare: Paraplegia that involves the lower back of the body to involve both legs, the disappearance or reduction of voluntary movements (paralysis), nerve impairment-sensory loss (neuropathy), inflammation of the membrane surrounding the SPİNAL cord (arachnoiditis)

Cardiac Disorder

Very common: Slow heart rate

Rare: Sudden cardiac arrest

Vascular Disorder

Very common: Low blood pressure (hypotension) and related dizziness or blackening

Gastrointestinal Disorder

Common: Vomiting

Respiratory, Chest Disorders and Mediastinal Disorder

Rare: Difficulty in breathing

Kidney and Urinary Tract Disorder

Common: Unable to void, incontinence

Musculoskeletal System Disorder:

Uncommon: Transient muscle weakness, back pain

General Disorders and Application Site Disorder

Very common: Nausea

Some symptoms may occur if injection is accidentally administered incorrectly or in combination with other local anesthetics. These symptoms include; seizures (crises), lightheadedness, blackening, tremor and numbness in the tongue.

Possible side effects observed with other local anesthetics, which may also be caused by BUSACAİN SPİNAL HEAVY:

• Rare: Damaged nerves (may cause permanent problems).

• If an excessive amount of BUSACAİN SPİNAL HEAVY is given to the spinal fluid, numbness may occur throughout the body (anesthesia).

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BUSACAİN SPİNAL HEAVY

Keep BUSACAİN SPİNAL HEAVY out of the sight and reach of children, and in its

packaging.

Store at room temperature below 25°C.

Do not freeze. Do not unfreeze if the drug is frozen.

Your doctor or hospital will store BUSACAİN SPİNAL HEAVY and will be responsible for quality of drug product if not used immediately after opening. Also be responsible for correct destruction of unused BUSACAİN SPİNAL HEAVY.

Use in compliance with the expiry date.

Do not use BUSACAİN SPİNAL HEAVY after the expiration date stated on the packaging.

Do not use BUSACAİN SPİNAL HEAVY if you notice any damage in the product and/or its package.

Do not dispose BUSACAİN SPİNAL HEAVY that is not used in order to protect the environment to city water or trash. Consult your pharmacist about this issue.

Marketing Authorization Holder:

HAVER FARMA İlaç A.Ş.

Akbaba Mahallesi Maraş Cad. No: 52/2/1 Beykoz / İstanbul

Manufacturing Site:

OSEL İlaç San. ve Tic. A.Ş.

Akbaba Mah. Maraş Caddesi No:52 Beykoz / İstanbul

This patient information leaflet was approved on 02/12/2015.

FOLLOWING INFORMATION IS FOR HEALTH PROFESSIONAL TO ADMINISTER BUSACAİN SPİNAL HEAVY

Administered by spinal injection. The recommended injection site is the L_3-L_4 intervertebral space.

SPİNAL injections should be performed only after it is confirmed that the subarachnoid area has been entered by lumbar puncture (clear cerebrospinal fluid seeps through the spinal needle or is seen during aspiration).

If the anesthesia fails, a new trial to administer the drug should only be made with a smaller volume and injection at a different level.

One cause of ineffectiveness may be poor distribution of the drug in the intrathecal area, which can be overcome by changing the patient's position.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BUSACAİN SPİNAL HEAVY 0,5% Ampoule Containing Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug substance:
Bupivacaine hydrochloride 5 mg / mL

Excipients:
pH of solution is adjusted with sodium hydroxide/hydrochloric acid (pH = 4.0-6.5).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear, colorless solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

BUSACAİN SPİNAL HEAVY is indicated for spinal (subarachnoid) anesthesia in surgical and obstetric procedures.

BUSACAİN SPİNAL HEAVY can be used for abdominal, urological and lower extremity surgical procedures lasting 1.5-3 hours.

4.2. Posology and method of administration

BUSACAİN SPİNAL HEAVY should only be used by or under the supervision of physicians with experience of regional anesthesia. Minimum possible dose should be used for suficient anesthesia.

The following dosage recommendations should be considered as a dose guide that can be used in an average adult, and the dosage should be individually adjusted to the patient.

The dose should be reduced in elderly patients and in the late stage of pregnancy.

High level of anesthesia	Injection site	Position of the patient	Dose		Onset of action (minutes)	Duration of action (hour)
			mL	mg		
L1*	L3/4/5	Sitting	1.5-3	7.5-15	5-8	2-3
T5**	L2/3/4	Couchant	3-4	15-20	5-8	1.5-2

* Lower extremity, urological and perineal surgery. The patient should be hospitalized for 2-3 minutes after the injection or if he feels faint.
** Lower abdominal operations (including Cesarean section). The effects of SPİNAL administration of bupivacaine over 20 mg have not been investigated.

Method of administration:
Administered by spinal injection. The recommended injection site is the L3-L4 intervertebral site.

SPİNAL injections should be performed only after it is confirmed that the subarachnoid area has been entered by lumbar puncture (clear cerebrospinal fluid seeps through the spinal needle or is seen during aspiration).

If the anesthesia fails, a new trial to administer the drug should only be made with a smaller volume and injection at a different level. One cause of ineffectiveness may be poor distribution of the drug in the intrathecal area, which can be overcome by changing the patient's position.

Additional information on special populations:
Renal / Liver failure:
The safety and efficacy of BUSACAİN SPİNAL HEAVY in patients with renal/hepatic impairment has not been studied. Special attention should be paid to patients with severe liver disease and severe renal impairment.

Paediatric population:
The safety and efficacy of BUSACAİN SPİNAL HEAVY in pediatric patients has not been studied.

Geriatric population:
The safety and efficacy of BUSACAİN SPİNAL HEAVY in geriatric patients have not been studied. The dose of BUSACAİN SPİNAL HEAVY should be reduced in elderly patients.

4.3. Contraindications

- In patients known to have hypersensitivity to bupivacaine hydrochloride, amide-type local anesthetics or any of the excipients,

- In diseases of the central nervous system (eg meningitis, tumors, poliomyelitis, intracranial hemorrhage),
- In patients with regional pyogenic infection at or near the injection site,
- In patients with spinal stenosis and active disease (eg spondylitis, tumors, tuberculosis) or trauma (eg spinal fractures),
- In patients with septicemia,
- It is contraindicated in patients with pernicious anemia by subacute SPİNAL cord degeneration.
- Spinal anesthesia should not be administered to patients in shock. Similarly, spinal anesthesia should not be administered to patients with coagulation disorders or to patients receiving ongoing anticoagulant therapy.

4.4. Special warnings and special precautions for use

It should be noted that spinal anesthesia can sometimes cause major blocks with paralysis in the intercostal muscles and diaphragm, especially in pregnant women.

Caution should be exercised in patients with grade II or III AV block as local anesthetics may reduce the conduction capacity of the myocardium. Special care should be taken in elderly patients and in patients with severe liver disease, severe renal dysfunction, or generally impaired general condition.

Since the use of bupivacaine and class III antiarrhythmic drugs may increase cardiac effects, patients treated with class III antiarrhythmic drugs (eg amiodarone) should be closely monitored and ECG data considered.

As with all other anesthetic drugs, bupivacaine can cause acute toxic effects on the central nervous system and cardiovascular system as a result of high concentrations in the blood. This may occur especially after accidental intravascular administration to vascular rich areas.

Ventricular arrhythmia, ventricular fibrillation, sudden cardiovascular collapse and death have been reported in association with high systemic concentrations of bupivacaine. However, high systemic concentrations at doses normally used for spinal anesthesia are not common. Uncommon in spinal anesthesia; however, a dangerous side effect is extensive or total spinal block resulting in cardiovascular depression and respiratory depression. While cardiovascular depression causes extensive sympathetic blockage, this may result in hypotension and bradycardia or even cardiac arrest. Respiratory depression may be caused by blocking the innervation of respiratory muscles, including the diaphragm.

There is an increased risk of generalized or total spinal block in elderly patients and in late-stage patients. Therefore, the dose of BUSACAİN SPİNAL HEAVY should be reduced in these patients.

Spinal anesthesia can lead to drop in blood pressure and bradycardia. The risk can be reduced by intravenous administration of crystalloidal or colloidal solutions. Decrease in blood pressure should be treated immediately with, for example, 5-10 mg ephedrine intravenously, and the injection should be repeated if necessary.

In rare cases, spinal anesthesia can cause neurological damage; this results in paresthesia, anesthesia, motor weakness and paralysis. Although neurological disorders such as multiple sclerosis, hemiplegia, paraplegia and neuromuscular disorders are not adversely affected by spinal anesthesia, attention should be paid.

BUSACAİN SPİNAL HEAVY contains less than 1 mmol (23 mg) of sodium per dose, ie it can be considered essentially free of sodium.

4.5. Interaction with other medicinal products and other forms of interaction

Caution should be exercised when using bupivacaine in combination with other local anesthetics or drugs that are structurally similar to local anesthetics (eg. Class IB antiarrhythmic drugs) as they have toxic effects.
Interaction studies on local anesthetics and class III antiarrhythmics (e.g.; amiodarone) are not available, but caution is advised in their use (see Section 4.4).

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women with child-bearing potential / Contraception

There is insufficient data on the use of BUSACAİN SPİNAL HEAVY in women of childbearing potential or on its effects on contraception.

Pregnancy

Studies on animals are insufficient in terms of effects on pregnancy / and-or / embryonal / fetal development / and-or / birth / and / or postnatal development. Use during pregnancy has no

known risk to the fetus. However, it should be kept in mind that the dose should be reduced for patients in late pregnancy (see section 4.4).
BUSACAİN SPİNAL HEAVY should not be used during pregnancy unless necessary.

Lactation

Bupivacaine is excreted in breast milk. However, at therapeutic doses of BUSACAİN SPİNAL HEAVY, no effect on the breastfed child is predicted. BUSACAİN SPİNAL HEAVY can be used during breastfeeding.

Fertility

No preclinical data on safety assessment are available.

4.7. Effects on ability to drive and use machines

In accordance with the dosage and route of administration, bupivacaine may slightly affect mental functions and temporarily cause movement and coordination problems. Patients taking this drug prouct should be warned not to drive or use machines.

4.8. Undesirable effects

Adverse effects caused by the drug itself, physiological effects of the nerve block (e.g., blood pressure decrease, bradycardia, transient urinary retention), events directly caused by needle puncture (e.g.; spinal hematoma) or events caused by needle puncture (e.g.; meningitis, epidural abscess) or cerebrospinal fluid leakage (e.g.; headache after lumbar puncture).

See Section 4.9 for information on symptoms and treatment of acute systemic toxicity.

The following terms and frequency ratings are used:
Very common (>1/10); common (>1/100 to <1/10); uncommon (>1/1000 to <1/100); rare (>1/10,000 to <1/1000); very rare (<1/10,000), unknown (cannot be estimated from the available data).

Nervous System Disorders

Common: Postdural puncture headache

Uncommon:	Paresthesia, paresis, dysesthesia
Rare:	Total unintentional spinal block, paraplegia, paralysis, neuropathy, arachnoiditis

Cardiac Disorders

Very common:	Bradycardia
Rare:	Cardiac arrest

Vascular Disorders

Very common:	Hypotension

Gastrointestinal Disorders

Common:	Vomiting

Respiratory, Thoracic and Mediastinal Disorders

Rare:	Respiratory depression

Kidney and Urinary Tract Disorders

Common:	Urinary retention, urinary incontinence

Musculoskeletal System Disorders:

Uncommon:	Muscle weakness, back pain

General Disorders and Application Site Disorders

Very common:	Nausea
Rare:	Allergic reactions, anaphylactic shock

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

4.9. Overdose

Acute systemic toxicity

Bupivacaine may cause acute toxic effects on the central nervous system and cardiovascular system if administered in high doses, especially intravascularly. However, the dose used in SPİNAL anesthesia is low and therefore the risk of overdose is unlikely. However, systemic toxic effects may occur because toxic effects are additive when administered simultaneously with other local anesthetics.

Treatment

Sufficient ventilation should be provided in cases of total spinal block (open airways, oxygen, intubation and, if necessary, controlled ventilation). In case of hypotension / bradycardia, a vasopressor with an inotropic effect should be administered.

In the event of signs of acute systemic toxicity, local anesthesia should be discontinued immediately. Treatment should be performed to ensure good ventilation, oxygenation and circulation.

Oxygen should always be given and ventilation should be added if necessary. Convulsions are treated with diazepam. Bradycardia is treated with atropine. Circulatory disorders should be treated with intravenously administered fluids, dobutamine and, if necessary, epinephrine (initially increased to 0.05 microgram / kg body weight / minute, if necessary, increasing to 0.05 microgram / kg body weight / minute every 10 minutes) and, in more advanced cases, hemodynamic monitoring should be performed. Ephedrine can also be tried. In case of circulatory arrest, resuscitation efforts should be demonstrated for several hours. All cases of acidosis should be treated.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Local Anesthetics
ATC code: N01B B01

Mechanism of action:
BUSACAİN SPİNAL HEAVY contains bupivacaine, a long-acting local anesthetic with amide structure. Bupivacaine reversibly blocks stimulation conduction in the nerves by inhibiting the permeability of sodium ions across the nerve membrane. Similar effects may also occur in the membranes of excitatory cells in the brain and myocardium.

BUSACAİN SPİNAL HEAVY is used in hyperbaric spinal anesthesia. The relative density of the solution for injection is 1.026 at 20 °C (equivalent to 1.021 at 37 °C), and the initial distribution to the subarachnoid space is significantly affected by gravity. For administration into the medulla SPİNALis, a relatively low concentration and a low dose are provided which provide a short-term effect. Dextrose-free bupivacaine formulations create a less predictable block but provide a longer duration of action than BUSACAİN SPİNAL HEAVY (containing dextrose).

5.2. Pharmacokinetic properties

General properties:

Bupivacaine has a high solubility in oil with an oil / water dispersion coefficient of 27.5.

Characteristics properties on patients

Absorption:

Bupivacaine shows complete and biphasic absorption from the subarachnoid space with a half-life of about 50 and about 400 minutes for the two phases with great diversity. The slow absorption phase is the rate determining factor in the elimination of bupivacaine, which explains why the virtual half-life is longer after intravenous administration.

Absorption from the subarachnoid space is relatively slow and gives a relatively low plasma concentration (approximately 0.4 mg / mL per 100 mg injected) with a small dose required for spinal anesthesia.

Distribution:

Bupivacaine crosses the placenta and the concentration of free bupivacaine is the same in the mother and fetus.

The rate of binding to plasma proteins is lower in the fetus than in the mother, resulting in a lower total plasma concentration in the fetus than in the mother.

Stable dispensing volume after intravenous administration is approximately 73 L.

Biotransformation:

Bupivacaine is substantially metabolized in the liver to 4 hydroxybupivacaine by mainly aromatic hydroxylation and to PPX by Ndealkylation; both pathways are mediated by

cytochrome P450 (CYP)3A4. Clearance is therefore dependent on liver perfusion and the activity of the metabolizing enzyme.

Elimination:

After intravenous administration, total plasma clearance was approximately 0.58 L / min, elimination half-life was 2.7 hours, and liver excretion rate was approximately 0.40.

Linearity/non-linearity:

Shows linear kinetics.

5.3. Preclinical safety data

No preclinical data for a safety assessment other than those mentioned in the Summary of Product Characteristic are available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Dextrose monohydrate

Sodium hydroxide/Hydrochloric acid

Water for injection

6.2. Incompatibilities

This medicinal product should not be mixed with other medicinal products as compatibility studies have not been carried out.

6.3. Shelf life

24 months

The solution should be used as soon as possible after opening the ampoule.

6.4. Special precautions for storage

Store at room temperature below 25°C.

Do not freeze. Do not use frozen products by unfreezing them

6.5. Nature and contents of container

At box, in transparent PVC separator Type I borosilicate 5 ml glass ampoule, 5 pcs

6.6. Instructions for use and handling and disposal

Unused products or waste materials must be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER

HAVER FARMA İlaç A.Ş.
Akbaba Mahallesi Maraş Cad. No: 52/2/1
Beykoz / İstanbul
Phone: 0216 324 38 38
Fax: 0216 317 04 98
E-mail: info@haver.com.tr

8. MARKETING AUTHORISATION NUMBER

2015/903

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation date: 02.12.2015
Renewal date of authorisation:-

10. DATE OF REVISION OF THE TEXT

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