PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Oxovasin solution - for topical application

Active substance: Reaction product in aqueous solution, produced from sodium chlorite, sodium hypochlorite, sulphuric acid 69%, potassium chlorate, sodium carbonate-hydrogen peroxide (2:3), sodium peroxide.

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

This medicine is available without a prescription. However, you still need to use Oxovasin carefully to get the best results from it. Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or health professional has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or any other health professional. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve.

In this leaflet

1. WHAT OXOVASIN SOLUTION IS AND WHAT IT IS USED FOR

Oxovasin solution is indicated for the local treatment of wounds and wound healing disorders.

Oxovasin solution is used for:
Treatment of wounds and wound healing disorders by improvement of wound cleansing, granulation and epithelization, and wound closure, including:

- Posttraumatic wound healing disorders, also with inflammation of the bone;
- Postoperative wound healing disorders, also with accompanying fistulae and wound cavities;
- Leg ulcers caused by venous insufficiency;
- Wounds in the case of circulatory disturbance after arterial occlusion.

You must contact your doctor if your symptoms worsen or do not improve.

2. BEFORE YOU USE OXOVASIN SOLUTION

Do not use Oxovasin solution
if you are allergic to Oxovasin or any other ingredients of Oxovasin solution listed in section 6.

During pregnancy, breast-feeding and in newborns Oxovasin may be used in life-threatening situations only as no data on human exposure are available. Experimental studies have not indicated any embryotoxic effect.

Warnings and precautions
Due to its mode of action, Oxovasin should be used as a monotherapeutic agent, i.e. no other medicine should be used. The application of additional topical medicines to the wound should be avoided under all circumstances since besides potential interactions most medicines counteract the wound healing effect of Oxovasin.

Using other medicines
Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Oxovasin should not be applied to the wound in combination with other topical medicines or dyes such as brilliant green, gentian violet, fuchsine and malachite green as these may impair the activity of the active ingredient.

Using Oxovasin solution with food, drink and alcohol
No special precautions required.

Pregnancy and breast-feeding
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 using this medicine.

During pregnancy, breast-feeding and in newborns Oxovasin may be used in life-threatening situations only as no data on human exposure are available. Experimental studies have not indicated any embryotoxic effect.

Driving and using machines
No special precautions required.

3. HOW TO USE OXOVASIN SOLUTION

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor, pharmacist or health professional if you are not sure.

Unless otherwise prescribed by your doctor, the recommended dose is:
Oxovasin should be applied twice daily to the wound or the wound cavity. On visually progressive wound healing this dosage may be reduced to once daily whereby the moistening principle of treating wounds should be maintained (e.g. use of physiological saline instead of the second dose).

The amount to be used depends on the size of the wound. For a wound size of 10 x 10 cm that can be covered by a folded sterile cotton compress of equal size, 5 ml Oxovasin is sufficient. The overall amount of the solution required depends on the size of the wound that can be covered by an appropriate number of cotton compresses. With large wound pockets and cavities, the amount of Oxovasin is determined by the number of loosely packed cotton compresses being used.

Between 5 to 10 ml Oxovasin can also be used when instilling fistula systems or deep wound cavities and pockets.

Method and frequency of administration
Prior to treatment, the area around the wound must be cleansed from all previously applied ointment and medication residues. These residues on the wound may be carefully washed off using physiological saline or may be showered off with normal tap water. Large areas of dead (necrotic) tissue should be treated surgically.

Oxovasin is applied to the wound either directly, by moistening the dressing material, or by instilling the medicine in fistulae and wound cavities.

The application of cotton compresses moistened with Oxovasin solution has proved successful in the treatment of wounds. Synthetic wound coverings can also be used. Use of an occlusive dressing is also possible (dressing impermeable to air and water).

Oxovasin is compatible with all dressing material that does not contain any active substances (e.g.: cotton compresses, synthetic wound coverings, foam rubber compresses, etc.).

Should the wound situation permit a once-daily change of dressing, the wound can be moistened by applying Oxovasin to the overlying dressing.

With deep wound pockets a cotton compress moistened with Oxovasin should be loosely packed into the wound pocket. This ensures that Oxovasin reaches deeper wound zones. Any pressure should be avoided in order not to impair the formation of new tissue (granulation).

In heavily secreting (discharging) wounds, the dressing should be changed twice daily in order to facilitate the removal of liquefied necroses (dead tissue). The excessive secretion of the wound normalizes during the treatment with Oxovasin.

Should the application of Oxovasin not be possible via dressing, the solution can also be applied into wound pockets and wound cavities via drainages. The application into fistula systems is also possible. For this kind of treatment, mechanical flushing with physiological saline prior to the application of Oxovasin is recommended. 5 to 10 ml Oxovasin is sufficient for this kind of treatment too.

In the case of prolonged bandaging intervals (e.g. Ulcus cruris, leg ulcer), Oxovasin can also be applied to the wound through a plastic tube inserted into the dressing.

Length of treatment
Length of treatment depends on the defined treatment goal. This can be three weeks (e.g. wound healing disorders) up to possibly several months (e.g. lower leg ulcer).

Please, talk to your doctor or pharmacist if you think that the effect of Oxovasin solution is too strong or too weak.

If you use more Oxovasin solution than you should

A single overdose does not require any special measures.

If you forget to use Oxovasin solution
Do not use a double dose when you forgot one. However, you can make up for a forgotten dose, unless the next dose is due shortly.

If you stop using Oxovasin solution
An interruption or premature termination of the treatment may delay the healing process of your wound. Please let your doctor know when you wish to terminate the treatment. No other special measures are required.

Please, comply carefully with the prescribed dosage scheme as otherwise Oxovasin solution will not have the desired effect.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or any other health professional.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects too, although not everybody gets them.

Possible side effects

Uncommon side effects (affect up to 1 in 100 patients) are the following side effects occurring in the wound region at the beginning of the treatment:

- Reddening of skin;
- Itching or burning sensations.

Rare side effects (affect up to 1 in 1,000 patients):

- Mild pain appears rarely at the beginning of the treatment.
- In rare cases hypersensitivity reactions (allergic contact dermatitis) caused by the active substance have been observed during the treatment with Oxovasin solution.

Potential accompanying symptoms and indications of wound healing are:

- Reddening of the wound margin;
- Itching or burning sensations, mild pain;
- Wound secretion with Ulcus cruris (leg ulcer) and Decubitus (pressure sore);
- Spontaneous bleeding;
- (Apparent) wound expansion.

Accompanying symptoms may be due to the exudation preceding the restorative phase of wound healing (emission of blood constituents caused by inflammation). These symptoms are predominantly observed in the treatment of venous ulcers in the lower leg and will normalize during the course of treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or any other health professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de.

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

5. HOW TO STORE OXOVASIN SOLUTION

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after "Expiry:". The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 25°C.
Keep in the original pack in order to protect from light.
For multiple uses, the bottle must be tightly closed immediately after withdrawal of a dose and stored in a dark place to avoid loss of efficacy. Any contact between the bottle opening and the skin or wound should be avoided.

Shelf life after opening of the bottle.
After first opening of the bottle, the shelf life of Oxovasin solution is 14 days.
Do not use this medicine if you notice the following: Yellow colouring of the aqueous solution that is normally clear.

Do not throw away any medicines via wastewater. 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 Oxovasin solution contains:

- The active substance is:
  5 ml solution contains:

  Reaction product 6.9 x 10^6 U*
  produced from 10.28 mg sodium chlorite, 1.38 mg sodium hypochlorite, 0.75 mg sulphuric acid 69%, 0.6 µg potassium chlorate, 0.37 mg sodium carbonate-hydrogen peroxide (2:3), 1.09 mg sodium peroxide.
  * *1 U. = 1 pmol ethylene released during the quantitative determination from aminocyclopropane-1-carboxylic acid in the presence of hemin as activator.*
- The other ingredients are:
  Glycerol, purified water

What Oxovasin solution looks like and contents of the pack

Oxovasin is a clear aqueous solution available in polyethylene bottles. The bottles are hermetically sealed. To open the bottle, the screw cap provided with an inner pin is turned to the right while overcoming the resistance.

Pack sizes:
50 ml and 100 ml.
Hospital packs (bundles) of 10 bottles of 50 ml each, 50 bottles of 50 ml each, 100 bottles of 50 ml each, 10 bottles of 100 ml each, 50 bottles of 100 ml each and 100 bottles of 100 ml each.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer
OXO Translational Science GmbH
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39164 Stadt Wanzleben – Börde

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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Oxovasin Lösung
Portugal:	Oxoferin, Solução cutânea
Hungary:	Oxoferin, oldat

This leaflet was last revised/approved in August 2016.

Further details about Oxovasin solution are available on www. oxovasin.de.

The effect of Oxovasin is based on its impact on the restoration of tissue. This is manifested in improved wound cleansing. Oxovasin improves the formation of granulation tissue and closes the wound by facilitating wound contraction and the restoration of the skin surface (epithelization) in the event of wound healing disorders.