

PACKAGE INFORMATION LEAFLET User information

Jacutin® Pedicul Spray

Allethrin I, piperonyl butoxide

Read the entire following package information leaflet carefully before you start using this medicinal product, as it contains important information.

Always use this medicinal product exactly as described in this leaflet or as advised by your doctor or pharmacist.

- Keep this leaflet. You may want to read it again.
- Ask your pharmacist if you require further information or advice.
- If you notice any undesirable effects, please contact your doctor or pharmacist. This also applies to undesirable effects not listed in this leaflet. See Section 4.

Jacutin® Pedicul Spray

What this leaflet contains:

1. What is **Jacutin Pedicul Spray** and what is it used for?
2. What should you consider before using **Jacutin Pedicul Spray**?
3. How should **Jacutin Pedicul Spray** be used?
4. What are possible undesirable effects?
5. How should **Jacutin Pedicul Spray** be stored?
6. Package content and additional information

1. What is **Jacutin Pedicul Spray** and what is it used for?

Jacutin Pedicul Spray is a spray for use against parasites, especially head-, pubic and clothing lice. **Jacutin Pedicul Spray** is used for infestations with head lice (*Pediculus capitis*), pubic lice (*Pediculus pubis*, *Phthirus pubis*) and clothing lice (*Pediculus corporis*).

Jacutin Pedicul Spray applied in exact accordance with these instructions destroys not only the lice themselves, but also their larvae and nits (lice eggs). At the very least, the larvae do not hatch or are not viable after hatching, thus interrupting the developmental cycle of the lice.

2. What should you consider before using **Jacutin Pedicul Spray**?

Jacutin Pedicul Spray should not be used

- if you are allergic to allethrin I and 5-[2-(2-Butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxol (piperonyl butoxide) or one of the other components of this medicinal product listed in Section 6.
- if you suffer from asthma or bronchopulmonary disorders.
- in the eyes or on mucous membranes

Warnings and precautions

Please talk to your pharmacist prior to using **Jacutin Pedicul Spray**. **Jacutin Pedicul Spray** is for external use only.

Jacutin Pedicul Spray is flammable. Do not spray onto flames or hot surfaces (such as hotplates). Treatment with **Jacutin Pedicul Spray** should not be carried out near naked flames (such as continuous flow water heaters). The treatment room should be well ventilated. Ingestion or inhalation of large quantities of **Jacutin Pedicul Spray** should be avoided. Larger quantities of **Jacutin Pedicul Spray** should not be sprayed in unventilated rooms.

Persons suffering from asthma or bronchopulmonary disorders should not inhale the spray, as it might irritate their mucous membranes to the extent that it might trigger an asthma attack.

Jacutin Pedicul Spray should not be used near an aquarium or terrarium because it is harmful to all cold-blooded animals (such as fish or reptiles etc.).

The propellant used is not harmful to the ozone layer.

Children

Babies should not be treated with **Jacutin Pedicul Spray**.

Administration/application of **Jacutin Pedicul Spray** together with other medicinal products

Inform your doctor or pharmacist if you are taking/using any other medication or have done so recently or if you intend to use/take any other medicinal products.

Decreased effectiveness of malathion is possible for the concomitant or immediately successive use of preparations containing malathion as an active ingredient.

Pregnancy and lactation

If you are pregnant or breastfeeding, if you suspect that you may be pregnant or if you intend to become pregnant, seek advice from your doctor or pharmacist prior to using this medicinal product.

Jacutin Pedicul Spray should not be used during the first three months of pregnancy, because animal experiments have indicated a risk of malformation, and no evidence regarding effects on humans are available.

Jacutin Pedicul Spray must not be used while breastfeeding.

Effects on ability to drive and use machines

No special precautions are required.

3. How should **Jacutin Pedicul Spray** be used?

Always use this medicinal product exactly as described in this leaflet or as advised by your doctor or pharmacist. Check with your doctor or pharmacist if you are uncertain.

For application to skin.

Unless prescribed otherwise, you should use **Jacutin Pedicul Spray** as follows:

If applied diligently, a single treatment suffices to kill all lice and nits or hatching larvae.

Treatment with **Jacutin Pedicul Spray** should be carried out in a well-ventilated room and away from open flames (such as continuous flow water heaters).

Lice stay tend to stay primarily within area of the hairline, i.e. close to the skin. For the best effect, it is thus important to spray **Jacutin Pedicul Spray** directly onto the skin or scalp.



Head lice

To use, flip the spray nozzle upwards. Spraying distance: 1-2 cm. To prevent greater scatter of the spray, which may for example cause irritation to the respiratory tract, the spray should be applied with one hand slightly cupped above the spray nozzle. If **Jacutin Pedicul Spray** is used in mass treatment (for example, in public health offices), as a precaution, the person administering the treatment is recommended to protect the shielding hand with a plastic or rubber glove (see "Undesirable effects").



Jacutin Pedicul Spray is applied to dry hair. For head lice treatment, the entire scalp hair including the hair on the neck and temples must be treated strand by strand. Hair length and density must also be taken into account. For shorter hair, a single short burst of spray (1-2 seconds) for each strand is enough; for longer hair, the nozzle has to be pressed twice until the hair is sufficiently and thoroughly moistened.

Start with the spraying treatment at the hairlines on neck, temples and forehead and proceed with the treatment towards the centre of the head.

After application, do not cover the hair.

30 minutes after treatment with **Jacutin Pedicul Spray**, wash hair with water and regular shampoo, and rinse repeatedly and carefully. Any remaining residual lice or nits can be combed out with a fine-toothed comb (nit comb, available in pharmacies).



To confirm treatment success, i.e. to check whether the first application had really destroyed all lice and nits, check after 8 days. If you again find lice or viable nits, repeat the treatment.

Should you still find lice or viable nits 8 days after this second treatment, please contact your doctor or pharmacist.

Because lice migrate easily, it is recommended during the infestation risk period (max. 12 days) to treat all family members except babies with **Jacutin Pedicul Spray**, under medical supervision, even if only one person was found to be affected by lice.

Pubic lice

For pubic lice treatment, the affected body areas (pubic hair, including perineal and leg hairs) are treated in the same way as described for head lice treatment. **Jacutin Pedicul Spray** is applied to dry hair. After 30 minutes, wash the body part treated with **Jacutin Pedicul Spray** using soap/syndet and rinse repeatedly and carefully. For persons with strong hair growth, pubic lice may also affect stomach, chest, lower arms, thighs, armpits, eyebrows and beard.

Important: cover eyes to protect from spray!

To avoid infection or re-infestation, it is also recommended to treat everyone who had come into close contact with the affected person.

Clothing lice

For a clothing lice infestation, garments affected by lice are treated with **Jacutin Pedicul Spray**. In such case, spray **Jacutin Pedicul Spray** evenly onto garments from a distance of approx. 20 cm. Pay particular attention to seams and hems. Repeat treatment after 8 days.

Please consult your doctor or pharmacist if you have the impression that the effect of **Jacutin Pedicul Spray** is either too strong or too weak.

If you have used a greater quantity of Jacutin Pedicul Spray than you should have

Poisoning is generally unlikely if the preparation has been used as intended. The administration form makes ingestion of the preparation highly unlikely. Should the preparation have been ingested (by accident or negligent intent), symptoms such as nausea, vomiting, diarrhoea and may occur.

Seek medical advice immediately after accidental ingestion or if symptoms of an overdose occur. There is no specific antidote. Treatment measures are essentially guided by the respective symptoms and have to be initiated as quickly as possible. After inhalation of large quantities of pyrethroids (including allethrin I), go to a well-ventilated room or ideally go outside.

If you have any further questions on the use of this medicinal product, please contact your doctor or pharmacist.

4. What are possible undesirable effects?

As with all medicinal products, this preparation can also have undesirable effects, though they may not necessarily affect everyone. The frequency of the occurrence of undesirable effects is based on the following categories:

Very common:	more than 1 in 10 people treated
Common:	1 to 10 in 100 people treated
Uncommon:	1 to 10 in 1.000 people treated
Rare:	1 to 10 in 10.000 people treated
Very rare:	fewer than 1 in 10.000 people treated
Not known:	frequency impossible to be assessed from available data

Localised sensitivity disorders (impaired skin sensation) was commonly reported after application of this group of active substances (pyrethroids).

Application of **Jacutin Pedicul Spray** can frequently result in itching and redness with a slight burning sensation, especially in blond infants with sensitive, delicate skin. These symptoms disappear 1-2 hours after hair has been washed.

A single case of an anaphylactic reaction in conjunction with the application of **Jacutin Pedicul Spray** has been reported.

Persons suffering from asthma or bronchopulmonary disorders should not inhale the spray, as it might irritate their mucous membranes to the extent that it might trigger an asthma attack.

If any undesirable effects occur, discontinue treatment with **Jacutin Pedicul Spray** and seek medical advice.

Accidental contact of **Jacutin Pedicul Spray** with eyes or mucous membranes (of mouth or nose) may result in local irritations. In such cases, rinse immediately and carefully with cold water. Ingestion or inhalation of large quantities of **Jacutin Pedicul Spray** must be avoided.

Reporting of undesirable effects

If you notice any undesirable effects, please contact your doctor or pharmacist. This also applies to undesirable effects not listed in this leaflet. You can also report undesirable effects directly to the Federal Institute for Medications and Medical Products, Dept. of Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting undesirable effects, you can help to increase the available information about the safety of this medicinal product.

5. How should Jacutin Pedicul Spray be stored?

Store this medicinal product out of the reach of children.

Do not use this medicinal product after the "Use by" expiry date on the package and container. The expiry date refers to the last day of the stated month.

Warning: Pressurised container. Do not expose to temperatures exceeding 50 °C (e.g. by exposure to sunlight). Do not open container by force.

Do not dispose of this medicinal product in wastewater or household waste. Ask your pharmacist about disposal when you have finished using this medicinal product. In this way, you help to protect the environment.

6. Package content and additional information

What does Jacutin Pedicul Spray contain?

- The active ingredients are allethrin I and 5-[2-(2-butoxyethoxy) ethoxymethyl]-6-propyl-1,3-benzodioxol (piperonyl butoxide). One aerosol container with 90 g (145 ml) of spray for application to skin, solution contains: Allethrin I 0.594 g; 5-[2-(2-butoxyethoxy) ethoxymethyl]-6-propyl-1,3-benzodioxol (piperonyl butoxide) 2.376 g.
- Other ingredients: Isododecane; propellant blend from 2-methylpropane, butane and propane.

What Jacutin Pedicul Spray looks like and package content:

Jacutin Pedicul Spray is a solution that is applied to the skin in the form of a spray.

Jacutin Pedicul Spray is available in packages of 90 g (145 ml) of spray.

Pharmaceutical company and manufacturer

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