Package insert

BEFORE USE
READ CAREFULLY ALL THE INFORMATION GIVEN IN THE PACKAGE INSERT
This medicinal product is for self-medication and can be used to treat easily recognisable, mild and transitory conditions that can be resolved without the help of a doctor.
It can therefore be purchased without a prescription, but must be used properly to ensure its efficacy and reduce the risk of any undesirable effects.
- Ask your chemist for any further information and advice
- See your doctor if the condition persists after a short period of treatment.

CONNETTIVINA
0.2% Cream
0.2% Gel
2 mg Impregnated gauze pads
4 mg Impregnated gauze pads
12 mg Impregnated gauze pads
200 mg/100 ml Cutaneous spray, solution
Hyaluronic acid sodium salt

Composition
CONNETTIVINA 0.2% Cream:
Active ingredient: hyaluronic acid sodium salt 2 mg/g (30 mg per tube of 15 g)
Excipients: polyethylene glycol 400 monostearate, decyl ester of oleic acid, emulsifying wax, glycerol, 70% sorbitol solution, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, sodium dehydroacetate, aroma (Dalin PH), purified water.
CONNETTIVINA 0.2% Gel:
Active ingredient: hyaluronic acid sodium salt 2 mg/g (60 mg per tube of 30 g)
Excipients: no-crystallizable 70% sorbitol, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, sodium dehydroacetate, carbomer 980, sodium hydroxide, purified water
CONNETTIVINA 2 mg Impregnated gauze pads
Each gauze pad (10x10 cm) is impregnated with 4 g of cream containing:
Active ingredient: hyaluronic acid sodium salt 2 mg
Excipients: glycerol, polyethylene glycol 4000, purified water
CONNETTIVINA 4 mg Impregnated gauze pads
Each gauze pad (10x20 cm) is impregnated with 8 g of cream containing:
Active ingredient: hyaluronic acid sodium salt 4 mg
Excipients: glycerol, polyethylene glycol 4000, purified water
CONNETTIVINA 12 mg Impregnated gauze pads
Each gauze pad (20x30 cm) is impregnated with 24 g of cream containing.
Active ingredient: hyaluronic acid sodium salt 12 mg
Excipients: glycerol, polyethylene glycol 4000, purified water
CONNETTIVINA 200 mg/100 ml Cutaneous spray, solution
Active ingredient: hyaluronic acid sodium salt 2 mg/ml (40 mg per 20-ml vial)
Excipients: sodium chloride, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, purified water

Presentation
CONNETTIVINA is presented in various forms for external use:
Cream: 15-g tube; 100-g tube; 30- gtube
Gel: 30-g tube
2mg Impregnated gauze pads: pack of 10 sterile gauze pads (10x10 cm) for cutaneous use.
4 mg Impregnated gauze pads: pack of 10 sterile gauze pads (10x20 cm) for cutaneous use.
12 mg Impregnated gauze pads: pack of 5 sterile gauze pads (20x30 cm) for cutaneous use.
Cutaneous spray, solution: vial with spray nozzle containing 20 ml of solution:

What it is
CONNETTIVINA is a wound-healing agent used to treat wounds and cutaneous ulcers.

Marketing Authorisation Holder
Fidia Farmaceutici S.p.A. – Via Ponte della Fabbrica 3/A – 35031 Abano Terme (PD) – Italy

Manufacturer and Final Controller
Fidia Farmaceutici S.p.A. – Via Ponte della Fabbrica 3/A – 35031 Abano Terme (PD) – Italy

Why it is used
CONNETTIVINA stimulates the repair and regeneration of the skin, accelerating the healing of abrasions, excoriations, superficial wounds, scalds, mild burns, cracked nipples.
CONNETTIVINA is also indicated in localised outbreaks of sore skin caused by physical agents such as the sun, cold, wind and nappy rash, and in irritated and dry skin caused by radiotherapy.
CONNETTIVINA can also be used as an aid in treatment for cutaneous ulcers of vascular origin, and slow-healing wounds such as bedsores.

When it must not be used
Hypersensitivity to its components or other strictly related substances from a chemical point of view.

When it is necessary to consult a doctor before using the product
There is no need to consult a doctor before using CONNETTIVINA.

What to do during pregnancy and breastfeeding
CONNETTIVINA can be used by pregnant and nursing mothers.

Precautions
Cleanse and disinfect the area to be treated before applying CONNETTIVINA.

What medical products or foodstuffs may modify the effect of CONNETTIVINA
No phenomena of interaction between CONNETTIVINA and antibiotics or other local treatments have ever been reported.
If you are using other medicinal products, ask the advice of your doctor or chemist.

It is important to know that
Use of the product, especially if prolonged, may give rise to sensitisation phenomena. Should this occur, consult your doctor before continuing the treatment.
The product does not interfere with the user's ability to drive or use machinery.

How to use the product
How much
Cutaneous spray, solution; Cream; Gel: treat the wound 2-3 times a day, applying enough product to cover the entire area evenly.
Impregnated gauze pads: apply one or more pads according to the size of the area to be treated, changing it/them 2-3 times a day.
WARNING: do not exceed the recommended doses without consulting a doctor.
When and for how long
WARNING: only use for brief periods of treatment.
If the condition persists, consult your doctor.
How
Cleanse and disinfect the wound carefully before applying CONNETTIVINA.
Cream and gel: apply a sufficient amount to cover the entire wound and spread evenly using a sterile gauze pad in the case of open wounds.
Impregnated gauze pad: remove from the sachet by the tip of the pad, apply to the wound and cover with a suitable bandage.
Cutaneous spray, solution: spray the solution evenly over the wound.

What to do if you have used too much
No manifestations of intoxication due to overdose of CONNETTIVINA have ever been reported.

The product is for external use only. In the case of accidental ingestion of an overdose of CONNETTIVINA, consult your doctor immediately or contact your nearest hospital.

Undesirable effects

No systemic-type undesirable effects associated with CONNETTIVINA have ever been reported. Occasional reactions of a local type have been recorded, but they were always mild and resolved spontaneously. Use of the product, especially if prolonged, may give rise to sensitisation phenomena.

Following the instructions given in the package insert will reduce the risk of any undesirable effects.

Should any such effects occur, however, it is advisable to consult your doctor or chemist.

It is important to inform your doctor or chemist of any undesirable effects that are not described in the package insert.

Ask your chemist for an Adverse Event Report Form (form B), and fill it in.

Expiry and storage

The expiry date indicated on the packaging refers to unopened product that has been correctly stored.

WARNING: do not use the product after the expiry date indicated on the packaging.

Keep out of the reach of children.

It is important to be able to consult the information on the product at all times, so do not discard the box or the package insert.

Package insert reviewed by the Italian Medicines Agency in March 2014