

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Intrinsa 300 micrograms/24 hours transdermal patch Testosterone

Read all of this leaflet carefully before you start using this medicine.

- Keep this 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. It may harm them, even if their symptoms appear to be the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Intrinsa is and what it is used for
2. What you should consider before you use Intrinsa
3. How to use Intrinsa
4. Possible side effects
5. How to store Intrinsa
6. Further information

1. WHAT INTRINSA IS AND WHAT IT IS USED FOR

Intrinsa is a transdermal patch which constantly releases small amounts of testosterone that is absorbed through your skin into the bloodstream. The testosterone in Intrinsa is the same hormone as that produced naturally in men and women.

After removal of the ovaries, testosterone drops to half of the levels compared to before the operation. Decrease in testosterone has been associated with low sexual desire, reduced sexual thoughts and reduced sexual arousal. All or any of these problems can cause personal distress or relationship difficulties. The medical term for this condition is Hypoactive Sexual Desire Disorder, also known as HSDD.

Intrinsa is used to treat HSDD.

Intrinsa is intended for use by women up to the age of 60 years who:

- have a low sexual desire which is causing distress or concern, and
- have had both of their ovaries removed, and
- have had their womb removed (hysterectomy), and
- are receiving estrogen therapy.

It may take longer than one month for you to notice an improvement. If you have not experienced a positive effect of Intrinsa within 3-6 months, you should inform your doctor, who will suggest that treatment be discontinued.

2. WHAT YOU SHOULD CONSIDER BEFORE YOU USE INTRINSA

Do not use Intrinsa

- if you are allergic (hypersensitive) to testosterone or any of the other ingredients of Intrinsa.
- if you know that you have had in the past, currently have, or think that you might have, breast cancer or any other cancer which your doctor has described as being caused or stimulated by the female hormone estrogen, also called 'estrogen-dependent' cancers.
- if you have other conditions that your doctor may consider not appropriate for the use of estrogen and/or testosterone.

Take special care with Intrinsa

- if you have a history of heart, liver or kidney disease.
- if you are diabetic, as testosterone may lower blood glucose levels.
- if you have a history of excessive adult acne, body or facial hair, hair loss, enlargement of the clitoris or voice deepening or hoarseness.

If you have any of the above, tell your doctor before you start to use Intrinsa. Your doctor will advise you on what you should do.

The efficacy of Intrinsa is reduced if your estrogen therapy is of a certain type ('conjugated equine estrogens'). Therefore, you need to discuss your type of estrogen with your doctor, who could advise you which type of estrogen is suitable together with Intrinsa. If you stop estrogen therapy you must also stop using Intrinsa. Keep in mind that estrogens should be administered for the shortest possible duration.

Use Intrinsa only as long as you experience a positive effect of the treatment. There is no information on the safety of Intrinsa beyond 12 months. There are limited data about the use in women above the age of 60.

It is not known whether Intrinsa increases the risk of breast cancer. Your doctor will carefully monitor you with regard to breast cancer.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Take particular care if you are taking medicines containing any of the following active substances:

- blood-thinning (anticoagulant) treatment

Children and adolescents

Intrinsa is not for use in children and adolescents.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Intrinsa is only indicated for women in their menopause after the ovaries and uterus have been removed. Do not use Intrinsa if you are, or suspect that you may be pregnant or are able to become pregnant, because it may cause harm to the unborn child.

Do not use Intrinsa in case of breast-feeding because it may cause harm to the child.

Driving and using machines

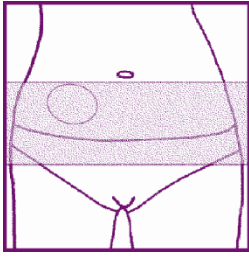
You can drive and use machines while using Intrinsa.

3. HOW TO USE INTRINSA

Intrinsa should be replaced twice weekly (each 3 to 4 days). The active substance is released from the patch constantly over 3 to 4 days and is absorbed through your skin. Always use Intrinsa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure of the instructions or if you want any more information.

Where to stick the patch

- Stick the patch onto your **lower abdomen**, below your waist. **Do not** stick the patch on the breasts or bottom.



Make sure that your skin at the application site is:

- ✓ clean and dry (free of lotions, moisturisers, and powders)
 - ✓ as smooth as possible (no major creases or skin folds)
 - ✓ not cut or irritated (free of rashes or other skin problems)
 - ✓ unlikely to be rubbed by clothing excessively
 - ✓ preferably free from hair.
- When changing your patch, stick the new patch on to a **different area** of the skin of your **abdomen**, otherwise you are more likely to cause skin irritation.
 - Only **one** patch is to be worn at a time.
 - If you are also using estrogen patches, make sure that the patch and the estrogen patch do not overlap.
 - For at least one week after removing a patch, do not place a new patch in the same area.

How to stick on the patch

Step 1 Tear open the sachet. Do not use scissors as you may accidentally damage the patch. Remove the patch. Apply the patch immediately after removing it from the sachet.



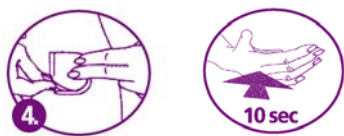
Step 2 While holding the patch, remove half of the protective liner that covers the sticky part of the patch. Avoid touching the sticky side of the patch with your fingers.



Step 3 Apply the sticky side of the patch to the selected area onto your skin. Press the sticky side of the patch firmly into place for about 10 seconds.



Step 4 Fold back the patch and carefully remove the other half of the liner. Press the entire patch firmly against your skin with the palm of your hand for about 10 seconds. Use your fingers to make sure the edges of the patch stick to the skin. If an area of the patch lifts, apply pressure to that area.



How to change your patch

- You will need to change your patch every 3 to 4 days, which means using **two patches each week**. This will mean that you wear one patch for 3 days and the other for 4 days. Decide which two days each week you are going to change your patch, and change the patch on the same two days each week.

For example: If you decide to start treatment on a Monday, then you have to change your patch always on a Thursday and a Monday.

- Sunday + Wednesday
- ✓ Monday + Thursday
- Tuesday + Friday
- Wednesday + Saturday
- Thursday + Sunday
- Friday + Monday
- Saturday + Tuesday

As a reminder, mark on the outer carton your chosen patch-change days.

- On the patch-change day, remove the used patch and immediately stick the new patch on to a **different area** of skin **of your abdomen**. Continue your treatment for as long as your doctor advises.
- Fold the used patch in half, sticking the patch to itself, and discard it in a safe way in order to keep it away from children (e.g. in a rubbish bin). Medicines should not be disposed of via wastewater (do not flush it down the toilet). Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

What about showering, bathing and exercising?

You may shower, bath, swim and exercise as normal while wearing the patch. The patch is designed to remain in place during these times. However, do not scrub the area where the patch has been placed too hard.

What about sunbathing?

Always make sure your patch is covered by clothing.

What if your patch becomes loose, lifts at the edges or falls off?

If a patch does begin to come off, you may be able to make it stick again by pressing on it firmly. If you cannot get the patch to stick successfully, remove the loose patch and use a new patch. Then continue with your regular schedule of patch-change days, even if this means discarding a patch after you have worn it for less than 3-4 days.

If you use more patches than you should

If you have applied more than one patch at a time

Remove **all the patches** sticking on to your skin and consult your doctor or pharmacist for further information on how to continue treatment with Intrinsa. Overdosing with Intrinsa is unlikely when used as directed, because once the patch is taken off testosterone is quickly removed by the body.

If you forget to use a patch

If you forget to change your patch

Change your patch as soon as you remember, and then continue with your regular schedule of patch-change days, even if this means discarding a patch after you have worn it for less than 3-4 days. Returning to your regular schedule will help you remember when to change your patch.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Intrinsa can cause side effects, although not everybody gets them.

Tell your doctor **immediately**:

- if you experience hair loss, enlargement of the clitoris, an increase in the amount of hair on the chin or upper lip, voice deepening or hoarseness, although these side effects may be mild. They are usually reversible if Intrinsa treatment is discontinued.

You should self assess for increased acne, increased hair growth in your face, loss of hair, deepening of your voice or enlargement of your clitoris, which all could be signs of adverse effects of testosterone, which is the active substance in Intrinsa.

- if you notice any skin reactions at the site of application such as redness, oedema, or blistering. In case of severe application site reaction, the treatment should be discontinued.

Very common side effects

The following side effects may occur very commonly (in more than 1 out of 10 patients) at the site of the skin where the patch is applied.

- rash
- irritation
- itching
- redness

Common side effects

The following side effects may occur commonly (in more than 1 out of 100, but less than 1 out of 10 patients), but most of them are mild in nature and reversible.

- increase in the amount of hair on the chin or upper lip
- hair loss
- acne
- migraine
- insomnia/inability to sleep properly
- voice deepening or hoarseness
- breast pain
- weight gain

If any of the side effects become serious, or if you notice any side effects mentioned above or side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE INTRINSA

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Do not refrigerate or freeze.

Do not use Intrinsa after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Intrinsa contains

The active substance is testosterone. Each patch contains 8.4 mg of testosterone, releasing 300 micrograms of testosterone over 24 hours.

The other ingredients are: Sorbitan oleate, 2-Ethylhexylacrylate – 1-Vinyl-2-pyrrolidone co-polymer.
Backing layer: Translucent polyethylene backing film printed with proprietary ink containing sunset yellow FCF (E110), latolrubine BK (E180) and copper phthalocyanine blue pigment.
Protective release liner: Siliconised polyester film.

What Intrinsa looks like and contents of the pack

Intrinsa is a thin, clear, oval patch with PG T001 stamped on the back.

The following pack sizes are available: 2, 8 and 24 patches. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.ema.eu.int/>