Do not take Estraderm MX
- If you have or ever had breast cancer, or if you are suspected of having it
- If you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any unexplained vaginal bleeding
- If you have excessive bleeding or heavy periods
- If you have any lung trouble (such as chronic bronchitis or lung cancer)
- If you have any kidney trouble
- If you have heart trouble or suffer from any heart complaints
- If you have diabetes
- If you have liver trouble
- If you have any blood disorder such as sickle cell disease
- If you have any mental or nervous disorder
- If you have any high blood pressure
- If you have any thyroid trouble
- If you have any epilepsy
- If you have any kidney trouble
- If you have a blood clotting disorder (such as von Willebrand's disease)
- If you have had varicose veins
- If you have ever had a blood clot in the leg or lung (pulmonary embolism)
- If you have a blood clotting disorder (such as protein S, protein C, or antithrombin deficiency)
- If you have had a blood clot before
- If you have had any problems with your liver (liver tests have not returned to normal)
- If you are allergic to estradiol or any of the other ingredients in this medicine
- If you are hyperthyroid (too active a thyroid gland)
- If you are pregnant
- If you are breast feeding
- If you have a blood clotting disorder which is passed on in your family
- If you have kidney trouble
- If you have had any of the above conditions appear for the first time while taking Estraderm MX
- Stop taking Estraderm MX, stop taking it at once and consult your doctor immediately.

When to take special care with Estraderm MX
Take special care with Estraderm MX
If you experience:
- difficulty breathing or swelling, tightness of the chest, hives, rash, general swelling of your body, face, neck and chest (flushes). Estraderm MX alleviates these symptoms after menopause. You will only be prescribed Estraderm MX if your symptoms seriously hinder your daily life.

Prevention of osteoporosis (for Estraderm MX 50 and 75 only)
During the menopause the amount of calcium in the bones of a woman's body drops. This can cause symptoms such as humps, a general rash, thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer). Taking oestrogen-only HRT will increase the risk of excessive thickness of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer). Taking a progestogen in addition to the oestrogen for at least 12 days of each month reduces this risk. So you will be prescribed a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen. In women who still have a womb and who are not taking HRT, on average, in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. (between 5 and 5.5 extra cases), depending on the dose and for how long it is taken. Estraderm MX 76 and Estraderm MX 100 contains a higher dose of oestrogen than other oestrogen-only HRT products. The risk of endometrium cancer when using Estraderm MX together with a progestogen is not known.

Breast cancer
Evidence suggests that taking combined oestrogen-progestogen and possibly also oestrogen-only HRT increases the risk of breast cancer. The risk depends on how long you take HRT. The additional increase becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment. For women who have had their womb removed and who are using oestrogen-only HRT for 5 years, little or no increase in breast cancer risk will be expected.

Regularly check your breasts. Your doctor if you notice any changes such as:
- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel

Ovarian cancer
Ovarian cancer is rare – much less than breast cancer. The use of oral oestrogen alone or combined oestrogen-progestogen has been associated with a slightly increased risk of ovarian cancer. The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 10000 will be diagnosed with ovarian cancer over a 5 year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 1 case). Other conditions

HRT will not prevent menopause. There is some evidence of a high risk of breast cancer in women who start using HRT after the age of 65. Speak to your doctor for advice.

Other medicines and Estraderm MX
Some medicines may interfere with the effect of Estraderm MX. This might lead to irregular bleeding. This applies to the following medicines:
- Oestrogens (such as conjugated oestrogen, oestradiol or oestrone)
- Progestogens
- Hormone replacement therapy products

Other medicines may interfere with the effect of Estraderm MX. This might lead to problems such as:
- St John's Wort

For signs of a blood clot, see 'Stop taking Estraderm MX and see a doctor immediately'.

Comparisons between users (i.e. about 1 extra case).

Comparisons between users (i.e. an extra 4 to 6 cases).
When and how to remove the patch

The patches should be changed twice a week on the same two days of the week, e.g. Monday and Thursdays. Choose two days which you are likely to remember.

When to start treatment
- If you are not currently using any form of HRT (patch or tablets), if you have recently started, or if you have been using a continuous combined HRT product (where oestrogen and the progestogen are given every day without interruption), you can start to use Estradem MX on any convenient day.
- If you are changing from a cyclic or sequential HRT treatment (where the progestogen is added for 12-14 days of the cycle), start to use Estradem MX the day after you complete the cycle.
- If you are still having periods you should start to use Estradem MX within 5 days of starting your period, irrespective of how long you bleed.

How long to use Estradem MX
It is important that you know the lowest possible effective dose and only as long as needed. You should apply a new patch twice a week, i.e. every 3 or 4 days.

From time to time, you should discuss with your doctor whether you still need the treatment

Where to apply Estradem MX
- Estradem MX patches are applied to the skin. You wear them all the time.
- Stick the patch on to a hairless area of skin below the waist. Most patterns find that the buttock is the best place. Choose an area of the buttock where the skin is not inflamed, broken, or irritated. You could also try the lower back, hip or abdomen.
- Never put a patch on or near the breasts. Choose a clean, dry area of skin. To help the patch stick, the skin should be clean, dry, and free of creams, lotions, oil, or powder. You should use a different area of skin each time. Wait a week before using the same area again. Avoid skin which is red or irritated.
- Do not expose the patch to direct sunlight.

How to apply Estradem MX
Each Estradem MX patch is seeded in an artichoke sachet. Tear open one of the sachets at the notch (do not use scissors) and take out the patch. Don’t take the patch out of the sachet until immediately before you intend to use it.

Removing the lining
A stiff, transparent protective lining covers the sticky side of the patch, i.e. the side that will be placed against your skin. First remove the smaller piece of the transparent liner. Then peel off the larger piece. Try to avoid touching the adhesive and remember not to allow the patch to become folded so that the sticky surfaces come in contact with each other. Now apply the patch.

Applying the patch
With the palm of your hand press the sticky side of the patch firmly onto the spot you have chosen. Hold it there for about 10-20 seconds. Make sure that it sticks well, especially around the edges, but once the patch is in place do not pull at it to test that it is sticking properly.

When you will find a table at the end of this leaflet for you to fill in to log your memory. Tick the day of the week on which you are starting the treatment and the day of the week to which the patch is to be applied (see Section 5), making sure that it is kept out of the reach of children because it will still contain some medication. Stick a new patch onto a different area of skin.

What to do if a patch comes off
If a patch falls off it will not stick to your skin again. Use another patch on a different area of your skin (see Where to apply the patch). Make sure you choose a clean, dry, lint-free area of skin. No matter what happens, go back to changing the patch on the same days as usual.

Further useful information
- Bathing, swimming, showering or exercising should not affect the patch if it has been correctly applied. You may wear the patch underwater in the swimming pool.
- Never apply a patch on a sweaty area or after a hot bath or shower. Wait until the skin is completely cool and dry.
- Do not remove the patch and try to put it somewhere else, it will not stick to your skin again. Instead apply a new patch in the usual way. Remember to apply your next patch at the normal time. If you have run out of patches, please contact your doctor straight away. (See also advice on 'What to do if a patch comes off'.
- Sunbathing: always make sure your patch is covered by clothing.
- Using a sunbed: cover up the patch.
- The drug in your patch is contained in the adhesive and not in a special reservoir.
- The drug in your patch is a gel which is colourless. This does not mean that the patch does not contain any medication.

If you use more Estradem MX than you should
Remove the patch if you have used too much Estradem MX. Symptoms of overdose are usually tenderness of the breasts and/or vaginal bleeding. Acute overdose is unlikely due to the way Estradem MX is used (patch). If symptoms persist contact your doctor.

If you forget to use Estradem MX
If you forget to apply a patch, apply a new patch as soon as you remember. No matter what day that happens, go back to changing the patch on the same day as usually you do. There is an increased chance of breakthrough bleeding or spotting if there is a break in treatment. Do not use a double dose to make up for the forgotten patch.

If you stop using Estradem MX
Stopping use of Estradem MX may increase the risk of breakthrough bleeding or spotting. Talk to your doctor if this occurs. After a long break in treatment, consult your doctor before starting to use the patch again.

If you have any further questions on the use of this medicine, ask your doctor. Your doctor or pharmacist can give you medical advice on the use of any medicines.

If you need to have surgery
If you are going to have surgery, tell the surgeon that you are taking Estradem MX. You may need to stop taking Estradem MX about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2). Blood clots in veins can cause deep vein thrombosis (DVT). Ask your doctor when you can start taking Estradem MX again.

4. Possible side effects

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

The following side effects are reported more often in women using HRT compared to women not using HRT:
- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started after the age of 65

For more information about these side effects, see Section 2.

Stop using Estradem MX immediately and tell your doctor if you develop any of the following:
- Serious allergic reaction may include rash, itching, hives, breathlessness or difficulty in breathing, wheezing or coughing, light-headedness, diziness, changes in levels of consciousness, hypertension, pain, fever, repeated vaginal bleeding or constant spotting.
- Tender, painful or swollen breasts
- Migraine or unusually severe headaches, or signs of stroke
- You become pregnant
- Signs of jaundice (yellowing of your skin or eyes).

The side effects listed below have also been reported:

- Very common, may affect more than 1 in 10 people:
  - Redness, pain and itching where the patch has been applied (signs of adhesion). This site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, edema, erythema, inflammation, pruritus, pain, redness, skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives and tistters
  - Tenderness, painful or swollen breasts
  - Breakthrough bleeding
- Common, may affect up to 1 in 10 people:
  - Headache
  - Rash, prickly or blotched, stomach ache
- Uncommon, may affect up to 1 in 100 people:
  - Breast cancer
- Rare, may affect up to 1 in 1,000 people:
  - Unusual weight changes, fluid retention (swelling or accumulation of fluid in the lower legs or ankles), leg pain
  - Dizziness
  - Very rare, may affect up to 1 in 10,000 people:
    - Blood clots, bruising, worsening varicose veins, raised blood pressure
    - Abnormal liver function test results, jaundice
    - Rash and itching over large areas of the skin. This sensitivity reaction is unlikely to become severe. If you are using the patch without talking to your doctor
    - Changes in the pigmentation in your skin (lightening or darkening of your skin colour)

Other side effects include:
- Dry eyes
- Contact lens discomfort.

Not known: frequency cannot be estimated from the available data
- Rapid changes in mood (e.g. depression, nervousness, etc.)
- Lightheadedness while in sex drive
- Migraine
- Dizziness
- Vomiting
- Gallbladder disorder (tendency to form gallstones)
- Headache
- Darkening of the skin particularly on the face or abdomen (terminal)
- Irregular heavy vaginal bleeding or constant spotting (possible signs of endometrial hyperplasia)
- Fibroids (benign growths in the uterus)
- Hives
- Muscle cramps
- Breast discharge
- Lumps in the breast (non-cancerous)
- If any of these apply to you and are severe, tell your doctor.

The following side effects have been reported with other HRTs:
- galbladder disease
- various skin disorders:
  - discolouration of the skin especially of the face or neck known as ‘pregnancy patches’ (chloasma)
  - pain over skin nodules (erythema nodosum)
  - rash with target or ring shaped reddening or sores (erythema multiforme)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellcard.

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

5. How to store Estradem MX
Keep out of the sight and reach of children.
Do not store above 25°C. Protect from light.
Do not use the patches after the expiry date which is stated on the carton and patch label after Exp.

The expiry date refers to the last day of that month.
Do not use if the patch is damaged or shows signs of tampering.

Remember if your doctor tells you to stop using this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

Treat your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active ingredient in Estradem MX is estradiol. The estradiol is derived from plants and is produced synthetically.

Each patch contains a total of 0.75mg estradiol.

The other ingredients are acrylate esters, isopropyl palmitate, polyethylene terephthalate, ethylene vinyl acetate copolymer.

The estradiol is released gradually while you are wearing the patch.

What Estradem MX looks like and contents of the pack
Estradem MX is 13mm rounded square, transparent, self-adhesive patch marked 'CG GPG. A one month pack contains 8 patches.

Manufactured by: Novartis Farma S.p.A. – Torre Annunziata, NA, Italy

Procured from within the EU and repackaged by the Product License holder: B&H Healthcare, Unit 4, Bradfield Road, Ruslip, Middlesex, HA4 6NU, UK

Estradem® MX 0.025mg, 21 patches, 18799/1879/2006

Fill this in to remind you when to change your patch. Please tick the box for the days of the week when you should change your patch.

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

Leaflet date: 13.07.2016

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