• if you have just given birth you are at an increased risk of
• if you have sickle cell anaemia (an inherited disease of the
• if you have diabetes
• if a close relative has or has ever had breast cancer
If the condition develops, or gets worse while you are using
Cleosensa or any other combination pill, and your doctor may
• if you are allergic to ethinylestradiol or drospirenone, or any
• if you have (or have ever had) a tumour in the liver
• if you have (or have ever had) angina pectoris (a condition
• if you need an operation or if you are off your feet for a long
• if you have (or have ever had) a blood clot in a blood

5. How to store

2. What you need to know before you take Cleosensa

Important things to know about combined hormonal
contraceptives (CHCs):

3. How to take

General notes

Out of 10,000 women who are not using any combined
contraceptives (CHCs):

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot with Cleosensa is small but some
problems may increase the risk of having a blood clot.

When should you contact your doctor?

RECOGNISING A BLOOD CLOT

Blood clots can develop
in the arteries (referred to as an 'arterial thrombosis' , 'arterial
embolism' or 'stroke'), in the veins (referred to as a 'venous
thrombosis' , 'venous embolism' or 'DVT') or in the heart.

•  a condition known as hyperhomocysteinaemia
•  very high blood pressure
•  severe diabetes with blood vessel damage

If you have any further questions, ask your doctor or
pharmacist. They are one of the most reliable reversible methods of
contraception if used correctly.

Amenorrhea

•  Out of 10,000 women who are not using any combined
contraceptives (CHCs):

Aromatase inhibitors

•  as you get older (particularly above about 35 years)
•  if you have a problem with your heart (valve disorder,
congestive heart failure or myocardial infarction)
•  if you get migraines, especially migraines with aura;
•  if you are overweight;
•  if you have (or have ever had) a blood clot in a blood
vessel;
•  if you have (or have ever had) a tumour in the liver;
•  if you have a problem with your liver (for example after
an operation) or stomach;
•  if you have a blood clot in the eye;
•  if you have angina pectoris (a condition
which causes severe chest pain and may be a first sign of a
heart attack);
•  if you have high blood pressure;
•  if you have (or have ever had) a blood clot due to
Cleosensa; or
•  if you have a medical condition that increases the risk of
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Cleosensa; or
•  if you have a medical condition that increases the risk of
having a blood clot.
Take the forgotten tablet as soon as you remember, even if this means taking it at a different time of day than usual. If you forget to take a tablet, follow the advice below:

- More than one tablet forgotten in this strip (diagram below):
  - If you forget to take more than one tablet, you need to take extra tablets from the next strip. Take as many as possible and then follow the normal way of taking tablets. You may need to start using a so-called barrier method during the first seven days of the next strip (see section 4.1) OR you can choose to delay your next period. If you choose to delay your period, you will need to make an extra tablet-free period of 7 days.

Continue taking the tablets at the usual time and use the remaining tablets as usual. If you are taking tablets in a strip and you have not taken all the tablets in that strip, you should complete the strip before you start the next.

5. How to use Cleosensa

Always take the tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Cleosensa is a combined contraceptive pill, containing 3 mg of drospirenone and 30 mcg of ethinylestradiol. It comes as a strip of 21 tablets and 7 tablet-free days (otherwise called a stop or gap week) bleeding should occur at the end of every cycle. You should use a barrier method of contraception (for example, a condom) during the first seven days of each cycle (that is the first 7 days of the first strip and the first 7 days of any other strip) to give you extra protection against pregnancy.

Cleosensa contains lactose. People who have severe binary lactose intolerance, galactosemics, Lapp lactase deficiency orFabry’s disease should not take this medicine.

Driving and using machines
It is unlikely that you will have any problems while driving or using machines. If you have any doubts, however, tell your doctor or pharmacist. You may still be able to drive and use machines, but you should let your employer know what you are taking.

6. What to do in case of trouble

If you forget to take a tablet

• If you forget to take a tablet, you should take the tablet you have missed as soon as you remember. It is very unlikely that a single missed tablet will cause you to become pregnant. If you are in doubt, please consult your doctor.

• If you forget to take a tablet, you should take as many tablets as possible from the next strip and then continue to take tablets at the usual time. You may need to start using a so-called barrier method during the first seven days of the next strip (see section 4.1) OR you can choose to delay your next period. If you choose to delay your period, you will need to make an extra tablet-free period of 7 days.

• If you have missed any tablets during your first strip, you will need to take extra tablets from the next strip. Take as many as possible and then follow the normal way of taking tablets. You may need to start using a so-called barrier method during the first seven days of the next strip (see section 4.1) OR you can choose to delay your next period. If you choose to delay your period, you will need to make an extra tablet-free period of 7 days.

• If you are missing tablets from your second strip, you will need to take extra tablets from the third strip. Take as many as possible and then follow the normal way of taking tablets. You may need to start using a so-called barrier method during the first seven days of the next strip (see section 4.1) OR you can choose to delay your next period. If you choose to delay your period, you will need to make an extra tablet-free period of 7 days.

• If you stop taking Cleosensa

You can stop taking Cleosensa whenever you want. If you do stop taking Cleosensa, you should continue to use a barrier method of contraception (for example, a condom) during the first seven days of the next strip (see section 4.1) OR you can choose to delay your next period. If you choose to delay your period, you will need to make an extra tablet-free period of 7 days.

• If you start taking Cleosensa

You can start taking Cleosensa at any time, provided you start taking a tablet on the first day of your menstrual period. If you start taking Cleosensa during the first 7 days of your period, you can delay your next period. If you delay your period, you will need to make an extra tablet-free period of 7 days.

• If you are pregnant or breast-feeding, think you may be pregnant or you are not sure when to start Cleosensa

If you think you may be pregnant, you should take a pregnancy test. If you are pregnant or breast-feeding, you should not take Cleosensa. If you become pregnant while taking Cleosensa, contact your doctor as soon as possible. Cleosensa will not prevent you from becoming pregnant again.

• If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormone contraceptives can affect the results of some tests.

You can stop taking Cleosensa and start using another method of contraception. People who are breastfeeding should not stop using Cleosensa. If you stop using Cleosensa, your periods will become irregular or you may have heavy periods. If you want to become pregnant, you should stop taking Cleosensa and use a so-called barrier method of contraception (for example, a condom).

Cleosensa contains two active substances: drospirenone and ethinylestradiol. The drospirenone component is similar to chlormadinone acetate. Cleosensa also contains the following passive ingredients in addition to the active substances:

- Lactose
- Sodium benzoate
- Sorbic acid
- Hydroxypropyl methylcellulose
- Methylparaben
- Propylparaben
- Sorbitol
- Triacetin
- Talc
- Talcum powder
- Water

Wear a so-called barrier method of contraception during the first seven days of the strip you are starting. This is because the contraceptive effect of the hormonal contraceptives is not immediately effective. You should use a so-called barrier method of contraception (for example, a condom) during the first seven days of each cycle (that is the first 7 days of the first strip and the first 7 days of any other strip) to give you extra protection against pregnancy.

7. How to store Cleosensa

Store below 25°C. It is important to keep this box out of the reach of children. Do not dispose of medicines via wastewater or household waste. If you think you may be taking too many Cleosensa tablets, report it immediately via the Yellow Card scheme. You can also report side effects directly via the Yellow Card scheme. By reporting side effects, you can help to detect any problems or side effects that may be due to this medicine.

For more information, please contact the MHRA: 020 7067 8000 or via the website at: www.mhra.gov.uk/yellowcard. By reporting

Learn more about the benefits and risks of this medicine.

8. Side effects

The possible side effects of this medicine are:

• Hormone related side effects: breast tenderness, breast enlargement, breast discharge, depression, mood swings, increased menstrual bleeding, changes in the timing or volume of menstruation, breast tenderness, breast pain, nausea, vomiting, dizziness, weight gain, obesity, change in appetite, change in body weight, acne, skin rash, severe itching, hair loss (alopecia), hair growth, high blood pressure, low blood pressure, high potassium levels in the blood, change in facial skin color, change in skin color, excessive hair growth, change in hair color, change in hair texture, chloasma, edema, premature closure of the epiphyses (growth plates in the bones), abnormal uterine bleeding, thick, whitish vaginal discharge and vaginal yeast infection.

• Blood clotting disorders

The chance of having a blood clot may be higher if you have any other reliable methods of birth control. If you want to become pregnant, you should stop taking Cleosensa and use a so-called barrier method of contraception (for example, a condom). If you have any further questions on this or any other medicines, please ask your doctor, pharmacist or other health care professional.