

AmnioSense™ is a unique detector liner that is easy to use and shows whether an amniotic leak is likely to have occurred. AmnioSense™ gives you peace of mind when you need it most.

Before using AmnioSense™, please read this leaflet in full because it contains important and useful information that you need to know.

This leaflet contains the following information:

1. About this product

- What is amniotic fluid and why test for fluid leaks?
- When amniotic fluid leaks may be more likely to occur
- How does AmnioSense™ work?
- What might affect the accuracy of the result?

2. Before you use

- Who should use AmnioSense™?
- What considerations should be taken before using AmnioSense™?

3. Using AmnioSense™

- How to use AmnioSense™
- How to interpret the results
- Why do I need to wait 10 minutes for the results?
- Reporting results to your doctor or midwife

4. Further information

- What does the AmnioSense™ pack contain?
- How to store AmnioSense™
- Performance Data

1. About this product

What is amniotic fluid and why test for fluid leaks?

Amniotic fluid is the protective liquid within the amniotic sac, which protects your baby during pregnancy. Leaking amniotic fluid could increase the risk of infection to both mother and baby, but early detection could help to prevent complications by confirming that you are experiencing leaking of amniotic fluid.

When amniotic fluid leaks may be more likely to occur

- During the last weeks of your pregnancy, before your expected due date
- 48 hours after an amniocentesis test
- Among women with a history of premature membrane rupture (breakage of the amniotic sac).

How does AmnioSense™ work?

AmnioSense™ has been created, with its unique composition, to detect amniotic fluid by testing the pH (acidity) levels and differentiating it from urine.

The liner has a central polymer-embedded strip which changes colour from yellow to blue, or green, when it comes into contact with fluid that has a pH level equal or higher than 6.5. This is because amniotic fluid always has a pH greater than 6.5, so its presence will normally cause this colour change to occur.

Even the smallest amount of amniotic fluid leakage will create a visible blue or green stain.

What might affect the accuracy of the result?

Antibiotic therapy or vaginal infections (such as bacterial vaginosis or trichomoniasis) can lead to an elevated vaginal pH level, which may result in a false-positive test result for the presence of amniotic fluid (i.e. showing a blue or green stain when amniotic fluid is not present).

2. Before you use

Who should use AmnioSense™?

AmnioSense™ can be used by pregnant women.

What considerations should be taken before you use AmnioSense™?

Do not use if:

- You have had sexual activity in the last 12 hours
- You have used vaginal douching soaps in the last 12 hours
- You are bleeding – report all occurrences to your midwife or doctor immediately
- You are taking any antibiotics
- You have (or have symptoms of) a vaginal infection such as bacterial vaginosis or trichomoniasis
- You are not completely dry after a shower or bath – any moisture may affect the test results
- You experience any skin sensitivity or irritation upon use – stop using AmnioSense™ and contact your doctor.

3. Using AmnioSense™

How to Use AmnioSense™

- Dry your hands and body completely before using this product
- Unwrap the individual AmnioSense™ liner
- Simply attach the AmnioSense™ liner to your underwear – the pale yellow strip should sit directly against your vagina
- Wear as you would a normal panty liner and continue your day as normal until you feel any wetness – each liner can be worn for up to 12 hours
- It is not advised that you use the liner when only lying down, since any fluid may not land on the polymer strip. The liner should be worn during your normal daily routine, while sitting, standing or walking, to allow gravity to assist in ensuring any liquid lands on the detector strip
- Once wetness has been experienced, you should remove the liner and wait 10 minutes before reading your result
- The liners are for single use only, so should be disposed of after use, as you would any other feminine hygiene product.



How to interpret the results

10 minutes after you have removed the liner from your underwear, look for a colour change. Make sure you have good lighting to read your results.

• Colour change to blue or green

If the liner turns blue or green (this colour change can be any size, shape or location, even if faint), this is an indication of probable amniotic fluid leakage.



PROBABLE AMNIOTIC FLUID LEAK

The colour change can look cloudy and can be more intense along part of the yellow strip edge. Consult your midwife or go to the hospital as soon as possible. Take the liner and this leaflet along with you to share the result.

• No colour change/remains yellow

If the liner remains or turns yellow (did not change colour) after 10 minutes, the vaginal wetness was probably not caused by amniotic fluid.



URINE LEAK

Dispose of the AmnioSense™ liner as you would any other feminine hygiene product.

If you continue to feel vaginal wetness, use a new liner.

Why do I need to wait 10 minutes for the results?

The liner may initially go blue and/or green before fading back to yellow within 10 minutes. It is therefore important to wait the full 10 minutes to interpret the final result.

Reporting results to your doctor or midwife

If the liner turns blue or green (any size, shape or location, even if faint) consult your midwife or doctor, or go to the hospital without delay.

If the result is not clear, or you feel uncertain, you should consult your midwife or doctor for further diagnosis.

Please note, amniotic fluid stains stay visible for at least 2 hours.

You should consult your midwife or doctor if you suspect you have a vaginal infection, are bleeding or experience any skin sensitivity or irritation upon use.

4. Further information

What does the AmnioSense™ pack contain?

The AmnioSense™ pack contains 12 tester liners and instructions for use.

How to store AmnioSense™

Store in a dry place and at room temperature. Please note the expiration date stated on the individual AmnioSense™ liner packaging.

Keep unused individually foil-wrapped AmnioSense™ liners sealed. Use immediately after opening.

If the liner is damaged or stained, do not use it.

Keep the product out of reach of children.

Performance Data

The AL-SENSE (name used for AmnioSense™ in clinical trials) demonstrated a sensitivity ranging from 95.7% to 100%. This means when tested on women where amniotic fluid is present, AmnioSense™ is likely to detect it in at least 95% of cases.

Manufacturer

CS Common Sense Ltd.
Haeshel St. 7, P.O.B. 3567, Caesarea 3088900, Israel.
www.cs-commonsense.com

EU Authorised Representative

Obelis s.a, Boulevard Général Wahis 53, 1030 Brussels, Belgium. www.obelis.net

Distributor

Ceuta Healthcare Ltd
Hill House, 41 Richmond Hill, BH2 6HS, England
www.ceutahealthcare.com

AmnioSense™ is a trade mark of CS Common Sense Ltd



This leaflet was last revised: 24/11/2016