

Colourstart® Test 65 mcg Cutaneous Patch

p-Phenylenediamine (PPD) 80 micrograms/cm²
(65 micrograms/patch)

**Read all of this leaflet carefully before you start using this medicine
because it contains important information for you.**

Colourstart is available without a prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Colourstart is and what it is used for
2. What you need to know before you use Colourstart
3. How to use Colourstart
4. Possible side effects
5. How to store Colourstart
6. Contents of the pack and other information



1. What Colourstart is and what it is used for

Colourstart is a ready-to-use patch test for finding out if you might be allergic to one of the ingredients (PPD) in hair colorants. PPD is present in more than two out of three hair colorants. PPD is known to cause allergic reactions, which may be severe, in some individuals.

If a substance to which you are allergic (an allergen) comes into contact with your skin it causes a reaction often called contact dermatitis.

The test consists of surgical tape with two patches. One of the patches (marked A+) is the active patch containing PPD. The other patch (marked A-) is the control patch with no PPD present.

Colourstart works by showing if you are allergic to the PPD patch (marked A+). If you are likely to be allergic to PPD then the skin under the patch (marked A+) will react to it becoming red and

inflamed and may have tiny blisters. If you have not shown an allergic response, the skin under this patch will not react. It will look normal and similar to the skin under the control patch (marked A-).

If your hair colorant recommends that you carry out an allergy alert test prior to application, Colourstart can be used instead of this test to test for allergy to PPD.

Colourstart works by showing if you are likely to be allergic to PPD only and will not detect if you might be allergic to other ingredients in hair colorants.

The absence of a reaction following use of Colourstart does not guarantee a safe hair colour treatment, but by using this product correctly, you can minimise the risk of reaction to hair colorant.

2. What you need to know before you use Colourstart

Do not use Colourstart if you

- suspect or know that you are allergic to PPD or any of the other ingredients of this medicine (See section 6).
- if you have active dermatitis on your skin (e.g. redness, swelling, itching)
- have previously experienced an allergy to hair colorant
- if you are pregnant or breast-feeding
- if you are taking oral or topical steroids and other immunosuppressant medicines

See section "Taking other medicines and Colourstart" below.

A temporary black henna tattoo may increase your risk of having an allergic reaction when you colour your hair.

DO NOT use Colourstart if you have a temporary black henna tattoo

DO NOT use Colourstart if you have had any reaction to a temporary black henna tattoo in the past.

DO NOT perform the "Allergy Alert Test" as instructed on hair colorants in addition to using this medicine. This is because repeated exposure of the skin to PPD whether in applying hair colorant, performing the "Allergy Alert Test" or in using Colourstart, may cause sensitisation (development of allergy) in some individuals. For this reason, Colourstart Test Patch should not be used more than once if you are using the same hair colour product, but may be repeated if you switch to a new hair colour product. **(See "Warnings and precautions: sensitisation").**

Colourstart is not recommended for adolescents and children under 16 years of age. Hair colorants are not intended for use by children under 16 years of age.

Warnings and precautions: sensitisation

In rare instances, you may become allergic to the PPD present on the Colourstart patch. This is also a risk with exposure to hair colorants containing PPD. Any reaction which occurs at the site of where the patch was applied, approximately 10 days later, may be a sign of contact sensitisation. If this happens talk to your doctor or pharmacist and **DO NOT** use hair colorants if this happens.

Talk to your doctor or pharmacist if you require further advice regarding use of this product or in deciding if it is suitable for you.

Take special care with Colourstart

- if you go out in the sun regularly, as you should avoid exposing the area where the patch is applied to the sun. This is particularly important during the summer.
- avoid getting the patch excessively wet as this may cause the patch to loosen and stop working properly. Take care therefore when bathing, showering or during periods of exercise where you may sweat.

Taking other medicines and Colourstart

Do not use Colourstart if you are taking oral or topical steroids (such as prednisolone, betamethasone, dexamethasone, fludrocortisone, fluticasone, hydrocortisone or immunosuppressant medicines (such as tacrolimus, cyclosporine, mycophenolate, azathioprine, sirolimus) as they may suppress a positive reaction. If you are unsure if any medicines you may be taking will interfere with Colourstart, you should speak to your pharmacist.

Pregnancy, breast-feeding and fertility

Pregnant women should not use Colourstart.

If you are pregnant or think you might be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

You should not use Colourstart if you are breast-feeding your baby.

Driving and using machines

There are no known effects of Colourstart on driving or using machinery.

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3. How to use Colourstart

Always apply the self-adhesive patch at least 5 days before any colouring process. This is because PPD sensitivity sometimes causes reactions which may not appear until 4 to 5 days after application.

Always use this medicine exactly as described in this leaflet.

Colourstart is not recommended for adolescents and children under 16 years of age.

Adults and adolescents aged 16 years and over:

The instructions and diagrams below relate to the use of the patch on the upper arm.

Select a clean, dry, intact area of skin to apply the patch. The patch should be applied only to healthy skin that is free of acne, scars, dermatitis or any other condition that may interfere with the test results. Avoid placing the patch on areas of the skin where creams or emollients have been applied as these may affect how the patch sticks to the skin.

Directions

1. Wash your hands before applying the patch.

2. Peel open the foil pouch and remove the patch.

Remove the tab marked "1" from the surface of the patch whilst taking care not to touch the patches (see Figure 1).

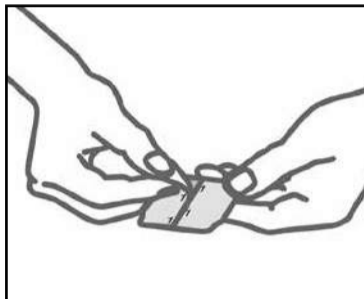


Figure 1

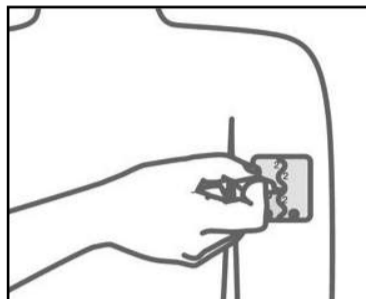


Figure 2

3. Whilst holding the patch at the edge with finger tips place it on the upper arm (above the elbow but below the shoulder) where you will be able to see the test results.

The patch should be smoothed from the centre to the outer edges (see Figure 2).

The second tab, marked with a "2" should then be removed (see Figure 3) and the patch smoothed from the centre to the outer edges (see Figure 2).

Once the patch is in place you will see one patch marked "A+", which is the active patch containing PPD and one clear patch marked "A-", which is the control patch with no PPD allergen.

You should wear the patch for at least 48 hours without removing it.

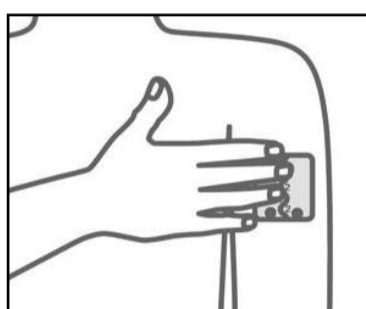


Figure 3

If you experience any symptoms of discomfort or there is a noticeable difference in how your skin looks or feels in this 48 hour period, remove the patch and wash the area gently with water as it may be a positive result. **DO NOT** apply hair colorant.

Talk to your pharmacist or doctor if you are at all unsure.

After 48 hours you may remove the patch.

Identifying the results

Wait 20 to 30 minutes after removing the patch and then examine your arm to look for any signs of an allergic "positive" test reaction. If the test is positive, indicating potential allergy to hair colorant, the area under the patch marked A+ will look different to that marked A-.

A positive result is usually seen as a rash, redness and tiny blisters. It may also itch and or feel warm. Note that the redness may not be evenly spread across the area.

If you see a reaction to Colourstart, **DO NOT** apply hair colorant.

You may suffer a worse reaction. You should seek medical advice from your doctor.

If a severe patch test reaction develops which is seen as intense redness with large fluid filled blisters, talk to your doctor immediately. DO NOT apply hair colorant.

If no positive test result is seen continue to look at the area for a further 48 to 72 hours to see if there is a change in the skin. There should be no visible differences in the two patches marked A+ and A-.

It is important to continue to look at the area for at least 5 days after initial application of the patch. This is because PPD sensitivity sometimes causes reactions which may not appear until 4 to 5 days after the application. If this occurs seek advice from your doctor.

Colourstart works by showing if you are likely to be allergic to PPD only and will not detect if you might be allergic to other ingredients in hair colorants. The absence of a reaction following use of Colourstart does not guarantee a safe hair colour treatment, but by following these safety instructions, you can minimise risk.

If you use more Colourstart than you should

This is not possible if you use Colourstart only as directed as it is a single use patch.

If you put on more than one patch, or if anyone else has put a patch on their skin accidentally, remove it as soon as you can and wash the area gently with water.

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

4. Possible side effects

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

The side effects could include:

- a flare-up of your dermatitis, if the test is used during an active phase of your skin disease.
- sensitisation to PPD on the test patch. A test reaction that occurs at the site where the patch was applied, approximately 10 days later, may be a sign of contact sensitisation (see section 2 above). If this happens talk to your doctor or pharmacist and **DO NOT** use hair colorants.
- a positive test reaction usually disappears within 1-2 weeks. On rare occasions, a positive test reaction may last for weeks or months. Such reactions will leave a temporary area of pale coloured skin (hypopigmentation) or darker coloured skin (hyperpigmentation).

- irritation and or itching caused by the surgical tape glue may occur, but usually disappears rapidly.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Colourstart

Keep this medicine out of the sight and reach of children.

Colourstart should be stored below 25°C.

Do not use Colourstart after the expiry date which is stated on the foil pouch. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the foil pouch is open or damaged.

The used patch should be folded, sticky sides together, put back in the empty pouch and disposed of carefully.

Always dispose of used Colourstart patches sensibly, away from the reach of children and animals.

6. Contents of the pack and other information

What Colourstart contains

- The substance in the 'active' (marked A+) patch is: p-Phenylenediamine (PPD) 65 micrograms.

The patch marked (A-) is the control, which does not contain PPD

- The other ingredients in the patches are: ethanol, povidone 90

What Colourstart looks like and contents of the pack

Colourstart consists of surgical tape with two patches. One of the patches (marked A+) is the active patch containing PPD. The other patch (marked A-) is the control patch with no PPD.

Colourstart is available as a single use self-adhesive plaster inside a foil pouch.

The foil pouch also contains a special type of paper or film (desiccant) to keep the patch fresh during storage.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder	Manufacturer
Trichocare Diagnostics Ltd	Smartpractice Denmark ApS
5 Beaumont Gate	DK-3400 Hillerød
Shenley Hill	Denmark
Radlett	
Hertfordshire WD7 7AR	

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