

First allergy test for hair dye to go on general sale

For the first time, people aged 16 years and older will be able to buy a medicinal screening test patch from general sale outlets to see if they are allergic to paraphenylenediamine (PPD), one of the most common ingredients present in hair dye, before colouring their hair.

Allergic reactions to this ingredient in hair dye can cause itchy rashes, redness and blisters. At its most severe, some people have even been admitted in A&E hospital departments.

The Colourstart Test is a self-adhesive plaster consisting of two patches, one containing 65 micrograms of PPD (active patch) and the other patch with no PPD (control patch). If there is a positive reaction to the test patch, which is applied to the upper arm, hair colourant should not be used.

The Medicines and Healthcare products Regulatory Agency (MHRA) has today announced that the Colourstart test will be formally reclassified from a prescription only medicine (POM) to a general sale list (GSL) medicine.

This change means people will be able to purchase the Colourstart Test, without the need for a doctor's prescription or a pharmacist's advice.

Making this test more widely available will allow people to screen for potential allergic skin reactions to PPD themselves, before applying hair colourant.

Widening public access to medicinal products when safe to do so, provides greater convenience and choice for the consumer. It also empowers individuals, allowing them to take control of their own health.

This decision was made following a robust assessment of the safety of the Colourstart Test, consideration by the Commission on Human Medicines (CHM) and a public consultation earlier this year.

Jan MacDonald, MHRA's Group Manager for Access and Information for Medicines and Standards (AIMS) in Vigilance and Risk Management of Medicines, said:

"The move to make the Colourstart Test more widely accessible will make it easier for people to screen for allergy to hair colourant and to avoid suffering skin reactions if they are allergic to PPD.

"Wider availability of medicinal products and improved patient access and choice remain high on the health agenda. The MHRA is committed to improving access to medicinal products for self-care where it is safe to do so."

NOTES TO EDITOR

1. The licence-holder for Colourstart Test Patch (Trichocare Diagnostics

Limited) applied to the MHRA to make this product available through general sales outlets.

2. PPD is present in more than 2 out of 3 hair dye products.
3. Responses to the public consultation are discussed in the [Public Assessment Report \(PAR\)](#) section 5; actual responses and names of organisations/professional bodies responding to the consultation are listed at the end of the PAR.
4. This medicine was licensed as a Prescription Only Medicine (POM) in 2012 and is not currently marketed.
5. To be reclassified from POM to GSL, a medicine must meet both the requirements of POM to Pharmacy (P) and P to GSL reclassification. Colourstart Test Patch was assessed firstly against the criteria for a medicine to be reclassified as P and then against the criteria for a medicine to be classified as GSL. Colourstart met the conditions of both POM to P and P to GSL reclassification. Further information on the POM and GSL criteria may be found in the [Public Assessment Report \(PAR\)](#) section 3.
6. The MHRA is responsible for regulating all medicines and medical devices in the UK. Underpinning all our work lies robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care (DHSC).