Package leaflet: Information for the user

TRUE TEST® 36

Plaster for provocation test

TRUE Test 36 consists of 3 strips of surgical tape, each strip contains 12 patches. 35 of the patches are coated with a film containing a specific allergen or a mix of allergens. One patch (patch no. 9) is a blank patch

Panel 1

		microgram/ cm²	microgram/ patch
1	Nickel sulphate	200	162
2	Wool alcohols	1000	810
3	Neomycin sulphate	600	486
4	Potassium dichromate	54	44
5	Caine mix[a)]	630	510
6	Fragrance mix[b)]	430	348
7	Colophony	1200	972
8	Paraben mix[c)]	1000	810
9	Blank patch	-	-
10	Balsam of Peru	800	648
11	Ethylenediamine dihydrochloride	50	41
12	Cobalt chloride	20	16

Panel 2

13	p-tert Butylphenol formaldehyde resin	45	36
14	Epoxy resin	50	41
15	Carba mix[d)]	250	203
16	Black rubber mix[e)]	75	61
17	CI+Me-Isothiazolinone	4	3
18	Quaternium-15	100	81
19	Methyldibromoglutaronitrile	5.0	4.1
20	p-Phenylenediamine	80	65
21	Formaldehyde[f)]	180	146
22	Mercapto mix[g)]	75	61
23	Thiomersal	7	6
24	Thiuram mix[h)]	27	22

Panel 3

		microgram/ cm²	mg/ pacth
25	Diazolidinyl urea	550	450
26	Quinoline mix[i)]	190	154
27	Tixocortol-21-pivalate	3.0	2.4
28	Gold sodium thiosulfate	75	61
29	Imidazolidinyl urea	600	490
30	Budesonide	1.0	0.81
31	Hydrocortisone-17-butyrate	20	16
32	Mercaptobenzothiazole	75	61
33	Bacitracin	600	490
34	Parthenolide	3.0	2.4
35	Disperse blue 106	50	41
36	2-bromo-2-nitropropane-1,3-diol	250	200

a) Five parts of benzocaine, one part of cinchocaine hydrochloride and tetracaine hydrochloride.
b) Five parts of geraniol and oak moss, four parts of hydroxycitronellal and cinnamylalcohol, two parts of cinnamaldehyde and eugenol and one part of isoeugenol and α-amylcinnamaldehyde.
c) Equal weights of methyl parahydroxybenzoate, ethyl parahydroxybenzoate, propyl parahydroxybenzoate, butyl parahydroxybenzoate and benzyl parahydroxybenzoate.
d) Equal weights of diphenylguanidine, zincdiethyldithiocarbamate and zincdibutyldithiocarbamate.
e) Two parts of N-isopropyl-N'-phenyl paraphenylenediamine, five parts of N-cyclohexyl-N'-phenyl paraphenylenediamine and five parts of N,N'-diphenyl paraphenylenediamine.
f) Actually contains N-hydroxymethyl succinimide.
g) Equal weights of morpholinylmercaptobenzothiazole, N-cyclohexylbenzothiazylsulphenamide and dibenzothiazyl disulphide.
h) Equal weights of disulfiram, dipentamethylenethiuram disulphide, tetramethylthiuram disulphide and tetramethylthiuram monosulphide.
i) Equal weights of clioquinol and chlorquinaldol.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TRUE Test 36 is and what it is used for
2. What you need to know before you use TRUE Test 36
3. How to use TRUE Test 36
4. Possible side effects
5. How to store TRUE Test 36
6. Contents of the pack and other information

1. What TRUE Test 36 is and what it is used for

TRUE Test 36 is used to test for allergic contact dermatitis. Contact dermatitis is a skin reaction caused by exposure to foreign substances resulting in an allergic reaction.

TRUE Test 36 is a ready-to-use patch test for determining the cause of allergic contact dermatitis.
TRUE Test 36 is for use in adults.

The test consists of 3 strips of surgical tape. The strips contains each 12 patches. Each patch is coated with a film containing a substance which might cause a skin reaction in sensitive people. Such substances are called allergens. Each patch contains a different allergen as well as one blank patch TRUE Test 36 contains 35 of the most common allergens/allergen mixes as well as one blank patch.

TRUE Test 36 works by showing if you are allergic to any of the test substances (allergens) on the patches. If a substance to which you are allergic comes into contact with your skin it causes an inflammatory reaction called contact dermatitis.

These substances could be an ingredient in your perfume or aftershave, in an ointment or cream, rubber gloves, industrial chemicals, etc. The substances in TRUE Test 36 are well-known allergens. If you are allergic to the substance in a particular TRUE Test 36 patch, then the skin under that patch will react to it, becoming red and inflamed. If you are not allergic to a particular patch, the skin under it will not react. You may be allergic to more than one patch.

2. What you need to know before you use TRUE Test 36

Do not use TRUE Test 36:
- If you suffer from severe or generalized dermatitis. The testing should be delayed until the acute course of dermatitis is over.
- If you are allergic to any of the other excipients in TRUE Test 36 (listed in section 6).

Warnings and precautions
You should avoid exposing the test area to the sun. Suntan may cause you to miss positive reactions to allergens you are actually allergic to.
- avoid sweating profusely while wearing the patch test strips.
- if you are taking medicines suppressing your immune system such as steroid medicines (e.g. prednisolone) or using steroid ointments/creams (e.g. hydrocortisone). These should not be used for at least two weeks before the test.
- if you have excited skin syndrome (angry back). This is a state of skin over-irritability caused by a reaction on other parts of the body. If you react to all of the patches, the doctor may need to repeat the test another day.
- If you have earlier had anaphylactoid reactions, the use of TRUE Test 36 should be considered carefully.

Talk to your doctor before using TRUE Test 36 if any of these factors apply to you. Your doctor will be able to decide what to do.

Sensitisation: In rare instances you may become sensitive to a substance on the patches while using TRUE Test 36. A test reaction that appears later than 10 days after application may be a sign of contact sensitisation.

TRUE Test 36 should only be applied to skin that is:
- free of acne
- free of scars
- free of dermatitis
- in a condition, which cannot interfere with the test results. You should check with your doctor if you are not sure.

Moisture around the test must be avoided. Therefore, when bathing or showering, you must be careful not to get the test panel or surrounding area wet. If the test panel does become wet it may loosen, allowing the test substances to be washed away.

Avoid any activity such as sunbathing or exercising, which may cause the patches to loosen.

Butylated hydroxyanisole (BHA) (E320) and Butylated hydroxytoluene (BHT)(E312) are present in allergen patch no. 7 Colophony (panel 1) for stability purposes. BHA and BHT may cause local skin reactions (e.g. contact dermatitis), so a false positive reaction for Colophony may occur.

The following information is intended for medical or healthcare professionals only:

An identification template is provided with each package of TRUE Test 36 for quick and easy identification of any allergen causing a reaction. To assure correct positioning, marks on the skin should correlate with the notches on the template. Notice the difference between page 1 and 2 on the template corresponding to Panel 1 and 2.

The interpretation method recommended by the International Contact Dermatitis Research Group is:

-	negative reaction
?	doubtful reaction: faint macular erythema only, no or very little infiltration
+	weak (nonvesicular) positive reaction: erythema, mild infiltration, possible papules
++	strong (vesicular) positive reaction: erythema, infiltration, papules, vesicles
+++	extreme positive reaction: intense erythema, infiltrate, coalescing vesicles
IR	irritant reaction of different types
NT	not tested

Note
- Patients showing a negative reaction may still be sensitised to another substance not included in this test panel. Furthermore, false-negative results may occur. Retesting or testing with complementary substances may be indicated.
- A positive reaction should meet the criteria for an allergic reaction (papular or vesicular erythema and infiltration).
- Pustules, as well as patchy follicular or homogeneous erythema without infiltration are usually signs of irritation and do not indicate allergy.

What is important in evaluating a positive test response is not the number of plusses assigned to the test response, but determining whether the response is a truly positive reaction (caused by allergy) or a non-specific irritant reaction.

All positive reactions should be carefully evaluated, considering clinical history and symptoms of the individual patient, particularly in case of positive reactions to specific allergens with lower relevant sensitisation rates (i.e. gold sodium thiosulphate).

Some of the allergens (neomycin sulphate,p-phenylenediamine, wool alcohols, caine mix, gold sodium thiosulfate, parthenolide, disperse blue 106, bacitracin, imidazolidinyl urea, diazolidinyl urea, budesonide, hydrocortisone-17-butyrate and tixocortol-21-pivalate) sometimes cause reactions, which may not appear until 4-5 days after the application. Patients should be instructed to report this. If appropriate, an additional office visit with a late reading at day 5-7 will verify a late reaction.

Contraindications
Severe or generalized dermatitis. The testing should be delayed until the acute course of contact dermatitis is over. Known hypersensitivity towards other excipients contained in the test besides the active substances

Special warnings and precautions for use
Sensitisation to a substance on the test panel only seldom occurs. A test reaction that appears on day 10 or later may be a sign of contact sensitisation.
Excited skin syndrome (angry back) is a state of hyperreactivity induced by dermatitis on other parts of the body or by a strong positive skin test reaction. Therefore, test results should be evaluated carefully in patients with multiple, positive, concomitant patch test results. To determine which reactions are false positive, retesting at a later date may be necessary.

The use of TRUE Test 36 in patients with known history of anaphylactoid reactions should be carefully evaluated before application.

Excessive sweating and sun exposure of the test site is to be avoided. Suntan may decrease patch test reactivity and cause false negative tests.

Avoid applying the test on skin with acne, scars, dermatitis or any other condition that may interfere with test results

If a severe patch test reaction develops, the patient may be treated with a topical corticosteroid or, in rare cases, with a systemic corticosteroid.

Butylated hydroxyanisole (BHA) (E320) and Butylated hydroxytoluene (BHT)(E312) are present as antioxidants in allergen patch no. 7 Colophony (panel 1). BHA and BHT may cause local skin reactions (e.g. contact dermatitis), so a false positive reaction for Colophony may occur.

Children
TRUE Test is not recommended for use in children, since its safety and efficacy have not been determined in these patients.

Other medicines and TRUE Test 36
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription, before TRUE Test 36 is applied. Remember that the skin specialist may not be aware of your other medicines.

Since steroids may suppress a positive test reaction, use of topical steroids on the test site or oral steroids equivalent to 20 mg prednisolone or more daily should be discontinued for at least two weeks prior to testing.

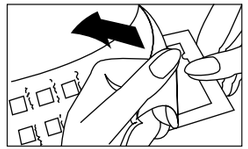
Pregnancy, breast-feeding and fertility
Pregnant women should not use TRUE Test 36. It is important to tell your doctor if you are pregnant or think you might be pregnant.

You should not breastfeed your baby while using TRUE Test 36

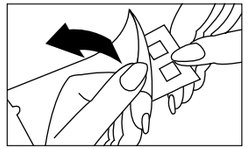
Driving and using machines
TRUE Test 36 is unlikely to affect your ability to drive or use machines. Talk to your doctor about this if you have any concerns.

3. How to use TRUE Test 36

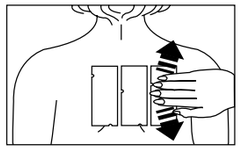
TRUE Test 36 is applied by your doctor.



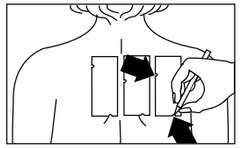
1. Peel open the package and remove the TRUE Test 36 panel.



2. Remove the protective plastic covering the surface of the panel. Be careful not to touch the test substances. A desiccant is included in the package for panel 2 for stability purposes.



3. Position the test on the upper back of the patient. However, the outer part of the upper arms is also acceptable. From the centre of the panel, smooth outward toward the edges, making sure each allergen makes adequate contact with the skin. The two panels are best positioned one each side of the backbone, a few centimetres apart. The third panel is placed next to one of the other panels.



4. The two notches on the panels (top left and in the lower edge) are indicated with a medical marking pen.

You should wear the test strips for 48 hours without removing them. You should be careful not to get the test area wet (water, sweat).

If the plaster is removed or detaches too early, it is possible that you could miss positive reactions to allergens that you are actually allergic to. Please contact your doctor if the plaster is removed or detaches before 48 hours.

After 48 hours you or your doctor may remove the panels.

When should the results be read?
Your doctor will read the test result half an hour after removal of the test and again 1-2 days after removal of the test, when any allergic reactions are fully developed and possible irritant reactions have faded. A few allergens sometimes cause reactions which may not appear until 4-5 days after removal of the test. Please inform your doctor if this happens.

What is the doctor looking for?
The doctor will carefully examine the test area for signs of an allergic reaction. This reaction usually consists of a rash with swelling, redness and tiny blisters. Redness alone, however, does not necessarily mean that it is an allergic reaction. If you are allergic, your doctor will provide you with the following information:
- Where in your everyday surroundings, you are likely to come into contact with the offending substances.

- How best to avoid these substances. Your doctor may suggest alternatives to the items you should avoid.

You should check with your doctor or pharmacist if you are not sure.

You should contact a doctor if you experience severe discomfort at the test site.

4. Possible side effects

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

Very common side effects (may affect more than 1 in 10 people):
- Irritation caused by the surgical tape adhesive may occur, but usually disappears rapidly.
- Burning sensation.
- Long-lasting test reactions. A positive test reaction usually disappears within 1-2 weeks, whereas a long-lasting test reaction may persist for weeks or months.

Common side effects (may affect up to 1 in 10 people):
- Test reactions may leave a temporary area of either pale or darker coloured skin.
- Redness of the skin caused by irritation or inflammation (erythema)

Uncommon side effect (may affect up to 1 in 100 people):
- A flare-up of your dermatitis.

Rare side effect (may affect up to 1 in 10,000 people):
- Sensitisation to a substance on the test panel may occur with patch testing.

Not known (frequency cannot be estimated from the available data)
- Anaphylactic reaction (systemic reaction, possibly with a life-threatening drop of blood pressure).
- Hypersensitivity (allergic reaction).

In extremely rare cases and only in relation to certain substances, anaphylactic reactions (systemic reaction, possibly with a life-threatening drop of blood pressure) have occurred. The allergy departments are for other reasons prepared to treat such incidences. Anaphylactic type reactions in relation to application of TRUE tests are not documented.

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 Yellow Card Scheme

Website: 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 TRUE Test 36

Store in a refrigerator (2°C – 8°C).

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

Do not use this medicine after the expiry date which is stated on the packing after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TRUE Test 36 contains
In addition to the active substances indicated on the first page, the test contains the following excipients: Tape of polyester fibres plus binder (ethylene vinyl acetate copolymer) with acrylic adhesive, polyester patches, povidone 90, hydroxypropylcellulose, methylcellulose, ß-cyclodextrin, sodium carbonate, sodium bicarbonate butylhydroxyanisole and butylhydroxytoluene.

What TRUE TEST 36 looks like and contents of the pack

Each panel is coated with a protective foil consisting of silicone-coated polyethylene and packed in sealed pouches of laminated foil.

The Panel 2 foil pouch also contains a desiccant to keep the allergens fresh during storage.

Contents of the pack: 10 test (1 test = one Panel 1, one Panel 2 and one panel 3).

Marketing Authorisation Holder and Manufacturer

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