

# MONOTEST

PURIFIED TUBERCULIN PROTEIN  
DERIVATIVE FOR HUMAN USE



## COMPOSITION

Tuberculin PPD .....	30 000 000 I.U.
Disodium phosphate .....	} sufficient quantity to insure pH and stability
Monopotassium phosphate .....	
Glycin .....	} not less than 80 g
Glycerin .....	
Phenol .....	not more than 0.5 g
Water for injections .....	up to 100 ml

## PHARMACEUTICAL DOSAGE FORM

Solution for multipuncture: applicator for multipuncture.

## MARKETING AUTHORIZATION HOLDER

Aventis Pasteur SA  
2, avenue Pont Pasteur, F-69007 Lyon

## INDICATIONS

Test for delayed hypersensitivity (allergy) to tuberculin (infection by tubercular bacillus or vaccination with BCG).

## PRECAUTIONS FOR USE

Avoid areas of skin affected by acne or covered with hair.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.

Keep out of the reach of children.

## DRUG INTERACTIONS AND OTHER INTERACTIONS

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or to your pharmacist.

## PREGNANCY - BREAST FEEDING

As a precaution, this medicinal product should only be used on pregnant and lactating women if it is particularly necessary.

As a general rule, during pregnancy and lactation, it is recommended always to ask your doctor or your pharmacist for advice before using a medicinal product.

## DOSAGE AND MODE OF ADMINISTRATION

### Application:

Administration route: multipuncture.

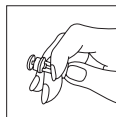
Clean the front of the forearm or deltoid with alcohol or ether.

Hold the applicator between your forefinger and middle finger, with the tips facing outwards. Use your thumb to apply pressure.

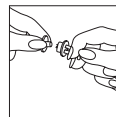
Carefully remove the protective cap by unscrewing lightly. Check that the tips are intact and impregnated.

Take a hold of the subject's forearm or deltoid, stretching the skin, and press the tips firmly on the area disinfected previously. Press firmly for at least 2 seconds: after correct application, the subject's skin should be marked with the circular print of the plate and that of the 9 tips coated with tuberculin.

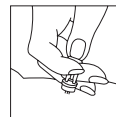
Do not wipe the area and wait for 3 to 4 minutes before allowing the patient to get dressed.  
Discard the test after use.



1. Hold the applicator between your forefinger and middle finger.



2. Carefully remove the protective cap by unscrewing lightly.



3. Press the loaded tips firmly on the disinfected area.

**Reading:** The reaction should be read 48 to 96 hours after application, preferably after 72 hours.

The reaction to be taken into consideration is the diameter of the induration, assessed by touching. Erythema without induration is not significant. From a size of 2 mm an induration is easy to measure.

The reaction is considered:

- negative when the size of the induration is less than 2 mm,
- uncertain when the size of the induration is between 2 and 4 mm,
- positive when it is greater than 5 mm.

An intradermoreaction (Mantoux test) may be performed in the event of an uncertain reaction.

## SIDE EFFECTS

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:

- Pain or itching may occasionally occur at the application point.
- Possibility of allergic reactions: urticaria, generalized allergy, oedema (infiltration of liquid in tissues), severe skin lesions.
- Exceptional cases of lymphangitis (inflammation of lymphatic vessels).

Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

## STORAGE

Do not exceed the expiry date stated on the external packaging.

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