

Differences Between the Summary of Product Characteristics of the Tuberculin PPD Solutions available from Chiron Vaccines Evans and SSI

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The following tables provide a summary of the differences between the licensed Tuberculin PPD dilutions manufactured by Chiron Vaccines Evans and the solutions available from Statens Serum Institute (SSI) as indicated in the latest Summary of Product Characteristics (SPC).

Presentations

Characteristics	Chiron	SSI	Recommendations/Notes
Presentation	1ml ampoules in a pack of 5 ampoules	1.5ml vials in a pack of 10 vials	The SSI vials have a chlorobutyl rubber stopper
Label Strength <i><u>NB. Please refer to the Dosage and Administration Section. 1 unit of PPD from SSI may not be equivalent to 1 unit of PPD from Chiron</u></i>	Not available 100 units per ml 1000 units per ml	2 units in 0.1ml 10 units in 0.1ml Not available	Caution advised due to the difference in the labelling format using units per ml (Chiron) compared to units in 0.1ml. (SSI). The use of decimal points in labelling can cause misinterpretation of the strength.

Dosage and Administration

Instructions	Chiron	SSI	Recommendations/Notes
Route of Administration	Intradermal	Intracutaneous*	Routes of administration are identical both mean 'within the skin'.
Method of administration	Similar advice is given in both SPCs.	Similar advice is given in both SPCs.	For further information please refer to the guidance on skin preparation and test site definition given in 'Immunisation against Infectious Disease 1996' (Green Book) section 32.15.2, page 231.
Routine Dose	Routine dose of (0.1ml) of 100 units per ml PPD (equivalent to 10 units).	SPC recommends an initial diagnostic test of 2 units in 0.1ml PPD.	Users are strongly recommended to follow the dosage instructions as indicated in the SSI SPC as the standard test for screening purposes.

Mantoux Test Results

Instructions	Chiron	SSI	Recommendations/ Notes
Test results	A positive reaction is characterised by an area of 5mm or greater of palpable induration, which may sometimes be surrounded by erythema. The results should be read 48 to 96 hours after the test, (preferably after 72 hours).	The reaction should be evaluated 48 to 72 hours after the injection. A positive reaction is defined as a flat, uneven, slightly raised induration having a diameter of at least 6 mm, surrounded by a more or less defined area of redness. <u>Only the induration is assessed.</u> The diameter of the induration in millimetres is measured transversely to the long axis of the forearm with a clear, flexible, plastic ruler.	Test results should be read after 48 to 72 hours. Thereafter reactivity is likely to wane. Please refer to the Green Book section 32.15.3, page 231.
Post Mantoux test BCG Vaccination	Tuberculin positive subjects should not be given BCG vaccine.	An indication of grading is given together with a list of reasons for a positive reaction. This does not include a statement on BCG vaccination.	Tuberculin positive subjects should not be given BCG vaccine. Please refer to the Green Book section 32.16, pages 231-232.

Contra-indications, Special Warning and Special Precautions for Use

Characteristics	Chiron	SSI	Recommendations/Notes
Contra-indications	None stated.	PPD should not be administered to patients known to be hypersensitive to any component of the medicinal products or to patients who previously have experienced a severe skin reaction to Tuberculin products.	
Other vaccines	Testing should not be carried out within three weeks of receiving a live viral vaccine.	No statement on the use of live viral vaccines.	Please refer to the Green Book section 32.17, page 232. Chiron guidance should be followed. Immunisation programmes should be arranged so the tuberculin testing is carried out before live vaccines are given.
Active tuberculosis	Caution should be exercised in the use of PPD in persons who have or are suspected of having active tuberculosis.	No similar caution.	2 units in 0.1ml is recommended for diagnostic screening.
Pregnancy and Lactation	PPD should only be used in pregnancy where the potential benefits of testing outweigh the possible risk of side effects.	Testing with PPD may be carried out during pregnancy and lactation.	The advice given in the SSI SPC applies.
Other warning and precautions.	Broadly similar advice is given in both companies SPCs. Please refer to the individual SPC for further information.	Broadly similar advice is given in both companies SPCs. Please refer to the individual SPC for further information.	For further information please refer to the SPCs and Green Book, page 232

Pharmaceutical Particulars.

Characteristics	Chiron	SSI	Recommendations/Notes
Excipients	Excipients listed in the Summary of Product Characteristics (SPC)	Minor difference in most excipients when compared with the Chiron' presentation. Product contains an additional excipient Potassium hydroxychinoline sulphate.	Control solution for Mantoux Test available from Chiron is not a suitable control for the SSI solutions.
Maximum Shelf life	12 months	36 months	
Instructions of use/handling	Use the contents of the ampoule as soon as possible and within 1 hour of opening provided adequate aseptic precautions are taken.	The contents of the vial should not be used more than 24 hours after the first dose has been removed.	Follow the SSI SPC instructions. It is recommended that the SSI vials are marked with the date and time of opening.
Storage	Between 2°C and 8°C. Do not freeze.	Between 2°C and 8°C	DH recommends that the product is not frozen.
Disposal	Disposal should be by incineration at a temperature not less than 1100°C at a registered waste disposal contractor.	Disposal in accordance with local requirements.	Disposal of all Tuberculin solutions from either manufacturer should be by incineration at a temperature not less than 1100°C at a registered waste disposal contractor.