Summary of Product Characteristics

1. Name of the medicinal product

C-TST

2. Qualitative and quantitative composition

The dose for each person is 0.1ml, each 0.1ml contains 5U Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).

This product is prepared with Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) obtained by fermentation, separation and purification of Escherichia coli highly expressing the gene of Mycobacterium tuberculosis ESAT6-CFP10, containing appropriate stabilizers, free of antibiotics.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Clear liquid for injection.

This product is a colorless and clear liquid, free of insoluble substances or impurities.

4. Clinical particulars

4.1 Therapeutic indication

This product is indicated for the diagnosis of Mycobacterium tuberculosis infection, and it is recommended for adults aged 18 - 65 years.

The skin test result with this product is not affected by Bacillus Calmette-Guérin (BCG) vaccine and it is suitable for the auxiliary diagnosis of tuberculosis (TB).

4.2 Posology and method of administration

Posology

This product is administered at 0.1 ml per human dose.

Method of administration

Use this product alone: Draw 0.1 ml (5 U) of this product and inject it intradermally on the palm side of the forearm using Mantoux method.

This product combined with TB-PPD: Draw 0.1 ml (5 U) of this product and 0.1 ml (5 IU) of TB-PPD, respectively, and inject this product intradermally on the palm side of the left forearm using Mantoux method. If no abnormality was observed after 5 minutes, inject PPD then on the palm side of the right forearm.

Determination of results

Use this product alone: The reaction at the injection site should be checked 48 ~ 72 h after injection, and the transverse diameter and longitudinal diameter (mm) of redness and induration should be measured and recorded, whichever is greater. Reactions with average diameter (sum

of transverse diameter and longitudinal diameter divided by 2) ≥ 5 mm are considered as positive reactions. Those with blisters, necrosis and lymphangitis are strongly positive reactions.

This product combined with TB-PPD: Check the reactions at the injection sites of both arms 48 ~ 72 h after injection. Select whichever the larger one of intradermal redness or induration for EC, and intradermal induration alone for TB-PPD. Measure and record the transverse and longitudinal diameters (in mm) of the redness and induration. The mean diameter of redness or induration of ≥ 5 mm indicates a positive reaction. Those with blisters, necrosis and lymphangitis are strongly positive reactions.

The specific results are determination as follows:

PPD	EC	Result Determination
-	-	No Bacille Calmette-Guerin (BCG) vaccination or negative conversion after BCG vaccination and no infection with Mycobacterium tuberculosis
+	-	Maintain positive after BCG vaccination
+/-	+	Mycobacterium tuberculosis infection

4.3 Contraindication

Do not use this product in patients with acute infectious diseases (such as measles, pertussis, influenza, pneumonia, etc.), acute ocular conjunctivitis, acute otitis media, extensive skin diseases and allergic constitution.

4.4 Special warning and precautions for use

The syringe and needle should be used to inject this product exclusively and not be used for other injections.

This product should not be used if the vial has cracks or foreign matter is in the product.

This product should be used within half an hour after opening.

Facilities for management of anaphylaxis should always be available while using this product.

Avoid subcutaneous or intramuscular injection.

4.5 Interaction with other medicinal products and other forms of interaction

Safe to use jointly with TB-PPD according to the clinical trials. Please see section 4.8 for details.

There are no interaction studies with other products or drugs other than those mentioned above

4.6 Pregnancy and lactation

Pregnancy

No data have been collected on the use of this product in pregnant women.

Lactation

No data have been collected on the use of this product in lactating women.

4.7 Effects on ability to drive and machine

This product has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned in section 4.8 may temporarily affect the ability to drive and use machines.

4.8 Undesirable effects

In the 7 clinical trials completed in China, a total of 3854 subjects were injected with this product, including 861 patients with tuberculosis, 443 patients with other non-tuberculous diseases, 1984 healthy subjects, 361 healthy subjects recently vaccinated (11-13 weeks) with BCG, and 205 healthy subjects vaccinated with BCG placebo. Most clinical studies were designed that EC and TB-PPD were injected on different arms of the same body. Systemic adverse reactions are the observed data when this product is used in combination with TB-PPD.

Incidence of adverse reactions recommended by the Council for International Organizations of Medical Sciences (CIOMS): very common (≥10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%), and very rare (< 0.01%); and the adverse reactions of this product are described as follows

Table 1 Incidence of Adverse Reactions

	Patients with TB and other non-tuberculous diseases	**Healthy Subjects**
Systemic ARs	Common: Pain, fever, fatigue, headache	Common: Fever
	Uncommon: Bradycardia or tachycardia, rash, petechiae, dizziness, polypnea, dysphoria and hypersensitivity.	Uncommon: Headache, nausea, fatigue, myalgia, diarrhea, vomiting, paresthesia
	Rare: Burning sensation, pruritus, contact dermatitis, tenderness, chill, chest pain, dry mouth, oropharyngeal pain, febrile sensation , skin pain, eye injury, lymphadenitis and allergic dermatitis	Rare: Chest discomfort, dizziness, decreased appetite, pruritus
Local ARs	Very Common: Itching at the injection site	Common: Itching /pain at injection site
	Uncommon: Pain, vasculitis and swelling at injection site.	Uncommon: Rash at injection site
	Rare: Hemorrhage, urticaria, necrosis, bruising and discoloration at injection site	Rare: Haemorrhage at injection site

Strongly positive reaction

This product can cause specific cutaneous allergic reactions at the injection site of tuberculosis bacillus infected persons, where local blisters, necrosis, lymphangitis are strong positive reaction. The results of phase III clinical trials (Study No. 005, 006, 007) showed that the incidence of local blister, necrosis and lymphangitis after injection was 3.82% (123/3221), 0.06% (2/3221) and 3.26% (105/3221), respectively.

Related Serious Adverse Events

One case of systemic allergic rash was observed in the phase III clinical trial of this product (Study No. 006), which was determined to be a serious adverse event possibly related to the injection of this product.

Safety of the second skin test

In the phase III clinical trial (Study No. 005), 318 BCG-vaccinated healthy subjects and 161 BCG-placebo-vaccinated healthy subjects underwent two skin tests before and 84 days after BCG or BCG-placebo vaccination. The safety observation data showed that the systemic adverse reactions were mainly fever, and the local adverse reactions were mainly itching at the injection site and pain at the injection site. The incidence was not significantly increased compared with the first skin test.

Pharmacovigilance

Submit adverse reactions reports to:

PT Jakarta Biopharmaceutical Industry

Jl. Musi no. 15, Cideng, Kec. Gambir, Jakarta Pusat 10150

Email : admin@jbio.co.id

Tel: +62-21-50208838

4.9 Overdose

No overdose has been documented.

5. Pharmaceutical properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Diagnostic Agents

ATC code: ATC code not yet available

Mechanism of Action

Using gene recombinant technology to effectively express the fusion protein ESAT6-CFP10 of the RD1 region of the mycobacterium in E-coli. Given the fact the gene of the RD1 region is not

present in BCG, therefore C-TST is only sensitive to the Mtb and will not cross-react with BCG. C-TST uses antigen-specific (ESAT6 & CFP10) immune response to detect Mtb infection, same with the principle of action used in IGRAs

Pharmacology

Over a concentration range of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) of 1–10 μg/ml, the skin test reactions of guinea pigs sensitized with live attenuated Mycobacterium tuberculosis CMCC (B) 93020 ($H_{37}Ra$) and virulent Mycobacterium tuberculosis CMCC (B) 95052 ($H_{37}Rv$) were positive and consistent. The skin test results of guinea pigs sensitized with dead Mycobacterium tuberculosis and guinea pigs sensitized with viable BCG were negative for this protein. The skin test reactions of guinea pigs sensitized with live BCG and dead Mycobacterium tuberculosis were positive and consistent by BCG-PPD and TB-PPD.

The study results showed that the skin tests of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) in guinea pigs sensitized by viable BCG and in guinea pigs sensitized by dead mycobacterium tuberculosis was negative, while the skin test in guinea pigs sensitized by viable mycobacterium tuberculosis was positive; TB-PPD showed positive reaction in the skin tests in guinea pigs sensitized by viable BCG, dead mycobacterium tuberculosis and viable mycobacterium tuberculosis.

Effectiveness

Table 2 Summary of completed clinical trials of this product

S/N	Study No.	Study Phase	Study Objective	Study Design and Type of Control	Investigational Drug, Dose Regimen and Administration Route	No. of Subjects	Basic Information of Subjects
1	001	Phase I	Safety/Tolerance	Single-center, randomized, open-labeled, uncontrolled	**Investigational drug:** EC (1 μg/ml, 5 μg/ml, 10 μg/ml, 20 μg/ml). **Dosing regimen:** Each subject received one dose; from low-dose group to high-dose group. **Administration route:** single-arm skin test.	24 Healthy Subjects	Healthy subjects aged 18~40
2	002	Phase IIa	Safety/dose exploration	Multicenter, randomized, open-labeled, controlled	**Investigational drug:** EC (1 μg/ml, 5 μg/ml, 10 μg/ml, 20 μg/ml), TB-PPD, EC placebo. **Dosing regimen:** Each subject received intradermal injection of TB-PPD or EC placebo in the left arm followed by an injection of EC in the right arm. Each subject received one dose of EC, from low dose to high dose successively. **Administration Route:** skin tests on the different arms of the same body.	56 healthy subjects and 88 patients with pulmonary tuberculosis, 144 in total	Healthy subjects and patients with pulmonary tuberculosis aged 18~65
3	003	Phase IIb	Dose determination/efficacy/safety	Multicenter, randomized, blinded, controlled	**Investigational drug:** EC (5 μg/ml, 10 μg/ml), TB-PPD. **Dosing regimen:** Blood samples were collected first for specific γ-IFN (T-SPOT) test, followed by skin test with TB-PPD and EC on different arms of the same body. **Administration Route:** skin tests on the different arms of the same body.	96 patients with pulmonary tuberculosis and 96 patients with non-tuberculous pulmonary disease, 192 in total	Patients aged 18~65 with pulmonary tuberculosis or non-tuberculous pulmonary disease

4	004	Phase IIb	Dose determination/efficacy/safety	Randomized, blinded, controlled	**Investigational drug:** EC (5 μg/ml, 10 μg/ml), TB-PPD, BCG, BCG placebo. **Dosing regimen:** Blood samples were collected first for specific γ-IFN (T-SPOT) test, followed by skin test with TB-PPD and EC on different arms of the same body, and then the population with negative results tested by three methods were screened; the subjects were blinded and randomized in a ratio of 1:1 to receive BCG or BCG placebo, and blood sampling and two-arm skin test were performed as above 12 weeks later. **Administration Route:** skin tests on the differentarms of the same body.	786 healthy subjects, 111 BCG vaccinated subjects and 111 BCG placebo vaccinated subjects	Healthy subjects aged 18~65
5	005	Phase III	Efficacy/safety	Randomized, blinded, parallel controlled	**Investigational drug:** EC (10 μg/ml), TB-PPD, BCG, BCG placebo; **Dosing regimen:** Blood samples were collected first for specific γ-IFN (T-SPOT) test, followed by skin test with TB-PPD and EC on different arms of the same body, and then the population with negative results tested by three methods were screened; the subjects were blinded and randomized in a ratio of 2:1 to receive BCG or BCG placebo, and blood sampling and dual-arm skin test were performed as above 12 weeks later. **Administration Route:** skin tests on the differentarms of the same body.	1564 healthy subjects, 318 BCG vaccinated subjects and 161 BCG placebo vaccinated subjects	Healthy subjects aged 18~65

6	006	Phase III	Efficacy/safety	Randomized, blinded, parallel controlled	**Investigational drug:** EC (10 μg/ml), TB-PPD; **Dosing regimen:** Blood samples were collected first for specific γ-IFN (T-SPOT) test, followed by skin test with TB-PPD and EC on different arms of the same body. **Administration Route:** skin tests on the differentarms of the same body.	745 patients with TB and 345 patients with other non-tuberculous diseases, 1090 in total	Patients aged 18~65 with TB or other non-tuberculosis diseases
7	007	Phase III	Efficacy/safety	Randomized, blinded, parallel controlled	**Investigational drug:** EC (10 μg/ml), TB-PPD; **Dosing regimen:** Blood samples were collected first for specific γ-IFN (T-SPOT) test, followed by skin test with TB-PPD and EC on different arms of the same body. **Administration Route:** skin tests on the differentarms of the same body.	46 patients with TB and 50 patients with other non-tuberculous diseases, 96 in total (both the patients aged ≥ 5 years and the patients aged < 5 years include 48 cases)	Patients aged < 18 years with TB or other non-tuberculosis diseases

The Phase III clinical studies for efficacy and safety confirmation of this product included 3 clinical trials (Study No. 005, 006, 007). In order to evaluate the diagnostic accuracy of EC for Mycobacterium tuberculosis infection, the TB patients clinically diagnosed in the above studies were used as the gold standard for Mycobacterium tuberculosis infection. The non-inferiority tests (non-inferiority margin value was -10%) of sensitivity between EC and T-SPOT, and between EC and TB-PPD were performed using the positive detection rate of EC, T-SPOT and TB-PPD as the sensitivity. Those with negative EC, T-SPOT, and TB-PPD test results screened in healthy subjects in the above studies were used as the gold standard for Mycobacterium tuberculosis uninfected persons, and these three methods were then performed in the populations 12 weeks after BCG placebo vaccination. The non-inferiority tests (non-inferiority margin value was -10%) of specificity between EC and T-SPOT, and superiority tests of specificity between EC and TB-PPD were performed using the negative conformity rate of EC, T-SPOT, and TB-PPD as the specificity. In order to evaluate whether EC is affected by BCG vaccination in the diagnosis of Mycobacterium tuberculosis infection, those with negative EC, T-SPOT, and TB-PPD test results screened in healthy subjects in the above studies were used as the gold standard for Mycobacterium tuberculosis uninfected persons, and these three methods were then performedin the populations 12 weeks after BCG vaccination. The non-inferiority tests of specificity between EC and T-SPOT (non-inferiority margin was -10%) and the superiority tests of specificity between EC and TB-PPD were performed using the negative conformity rate of EC, T-SPOT, and TB-PPD as the specificity.

(1) Sensitivity Results for the Diagnosis of Mycobacterium Tuberculosis Infection

The results of the clinical study in 791 patients with clinically diagnosed TB showed that the diagnostic sensitivity (positive detection rate) of EC was 90.64%, the diagnostic sensitivity of T-SPOT was 91.15%, and the diagnostic sensitivity of TB-PPD was 90.90% in this population. The difference (95% CI) in sensitivity between EC and T-SPOT was -0.51% (-2.39%, 1.36%), the difference (95% CI) in sensitivity between EC and TB-PPD was -0.26% (-2.36%, 1.80%), and the lower limits of confidence intervals were > -10%. The data are shown in Table 2:

Table 3 Sensitivity of EC in the diagnosis of Mycobacterium tuberculosis infection

Population Classification	Sensitivity (positive detection rate)			Difference of sensitivity (95% CI)	
	EC	**T-SPOT**	**TB-PPD**	**EC& T-SPOT**	**EC& TB-PPD**
TB Patients	717/791 (90.64%)	721/791 (91.15%)	719/791 (90.90%)	-0.51% (-2.39%,1.36%)	-0.26% (-2.36%,1.80%)
Adult pulmonary tuberculosis patients	608/667 (91.15%)	616/667 (92.35%)	608/667 (91.15%)	-1.20% (-3.22%,0.75%)	0.00% (-2.25%,2.25%)
Patients with bacteriological positive pulmonary	366/389 (94.09%)	369/389 (94.86%)	360/389 (92.54%)	-0.77% (-3.42%,1.79%)	1.55% (-1.27%,4.48%)

tuberculosis					
Patients with Bacteriological negative pulmonary tuberculosis	242/278 (87.05%)	247/278 (88.85%)	248/278 (89.21%)	-1.80% (-4.81%,1.40%)	-2.16% (-5.77%,1.42%)
Patients with pulmonary tuberculosis under initial treatment	531/583 (91.08%)	536/583 (91.94%)	530/583 (90.91%)	-0.86% (-2.91%,1.21%)	0.17% (-2.25%,2.58%)
Patients with retreatment pulmonary tuberculosis	77/84 (91.67%)	80/84 (95.24%)	78/84 (92.86%)	-3.57% (-10.11%,2.35%)	-1.19% (-6.70%,4.00%)
Adult patients with extrapulmonary tuberculosis	186/198 (93.94%)	188/198 (94.95%)	181/198 (91.41%)	-1.01% (-3.54%,1.44%)	2.53% (-1.11%,6.35%)
Adult patients with simple extrapulmonary tuberculosis	63/69 (91.30%)	63/69 (91.30%)	64/69 (92.75%)	0.00% (-4.17%,4.29%)	-1.45% (-7.97%,4.92%)
Pediatric tuberculosis patients	38/46 (82.61%)	35/46 (76.09%)	39/46 (84.78%)	6.52% (-4.76%,18.18%)	-2.17% (-13.33%,9.30%)

(2) Specificity Results for Diagnosis of Mycobacterium Tuberculosis Infection

The EC, T-SPOT and TB-PPD tests were conducted in 1564 healthy subjects. Among the 479 subjects with negative test results for the three methods, 318 subjects were vaccinated with BCG (2 subjects were missing) and 161 subjects were vaccinated with BCG placebo. The results of clinical study on 161 BCG placebo recipients showed that the diagnostic specificity (negative conformity rate) of EC, T-SPOT and TB-PPD was 88.20%, 93.17% and 60.87%, respectively. The difference (95% CI) in specificity between EC and T-SPOT was-4.97% (-9.32%, -0.62%), and the lower limit of confidence interval was > -10%. The difference (95% CI) in specificity between EC and TB-PPD was 27.33% (19.25%, 35.40%), and the lower limit of confidence interval was > 0. The data are shown in Table 3:

Table 4 Specificity of EC in the diagnosis of Mycobacterium tuberculosis uninfected population

Classification of Population	Specificity (Negative Conformity Rate)			Difference in Specificity (95% CI)	
	EC	T-SPOT	TB-PPD	EC& T-SPOT	EC& TB-PPD

BCG placebo recipients with negative test results of the three methods in healthy subjects	142/161 (88.20%)	150/161 (93.17%)	98/161 (60.87%)	-4.97% (-9.32%, -0.62%)	27.33% (19.25%,35.40%)

Note: In the second skin test of this product within 11-13 weeks, the rate of boosting reaction was11.80%, which was similar to 6.83% for T-SPOT and lower than 39.13% for TB-PPD.

(3) The results of specificity in the diagnosis of Mycobacterium tuberculosis infection after BCG vaccination.

The EC, T-SPOT and TB-PPD tests were conducted in 1564 healthy subjects. Among the 479 subjects with negative test results for the three methods, 318 subjects were vaccinated with BCG (2 subjects were missing) and 161 subjects were vaccinated with BCG placebo. The results of the clinical study in 316 BCG recipients showed that the diagnostic specificity (negative conformity rate) of EC, T-SPOT and TB-PPD was 92.72%, 95.25%, and 26.58%, respectively. The difference (95% CI) in specificity between EC and T-SPOT was -2.53% (-5.06%, 0.00%), and the lower limit of the confidence interval was > -10%. The difference (95% CI) in specificity between EC and TB-PPD was 66.14% (60.76%, 71.52%), and the lower limit of the confidence interval was > 0. The data are shown in Table 4:

Table 5 Specificity of EC for the diagnosis after BCG vaccination in persons uninfected with Mycobacterium tuberculosis

Classification of Population	Specificity (Negative Conformity Rate)			Difference in Specificity (95% CI)	
	EC	T-SPOT	TB-PPD	EC& T-SPOT	EC& TB-PPD
BCG recipients with negative test results of the three methods in healthy subjects	293/316 (92.72%)	301/316 (95.25%)	84/316 (26.58%)	-2.53% (-5.06%,0.00%)	66.14% (60.76%,71.52%)

(4) Test results in patients with other diseases other than tuberculous

The results of the clinical study in 394 patients with clinically diagnosed other non-tuberculous diseases showed that the positive detection rate of EC, T-SPOT, TB-PPD was 26.90%, 21.32%, and 40.36%, respectively. The data are shown in Table 5:

Table 5 Test results of EC in patients with other non-tuberculous diseases

Classification of Population	Positive Detection Rate		
	EC	T-SPOT	TB-PPD
Patients with other non-tuberculous diseases	106/394 (26.90%)	84/394 (21.32%)	159/394 (40.36%)

5.2 Pharmacokinetics properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of acute toxicity of intradermal injection, acute toxicity of intramuscular injection, intracutaneous stimulation test, hemolysis test, active systemic anaphylaxis test.

Acute toxicity test of intradermal injection and acute toxicity test of intramuscular injection

The mice were given Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) at 53.61μg/mouse and 0.2μg/mouse by single intradermal or intramuscular injection. The results showed that no abnormal reactions or deaths occurred during the whole test, and the body weights of animals in each group increased with the extension of the test duration during the test. No macroscopic abnormal lesion was observed in each organ and the skin at the injection site, indicating that no mouse showed significant acute toxic reaction or showed acute toxic target organ at the high dosage of 53.61μg/mouse and the equivalent dosage of 0.2μg/mouse after injection of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).\

Intracutaneous stimulation test

After a single intradermal injection of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) in rabbits, no skin erythema or edema was observed after administration. Routine histopathologic examination was conducted 72h after drug withdrawal. No significant swelling, ulcer, necrosis or other irritating lesions was observed in the local skin and subcutaneous tissue on the left and right sides of administration. The results showed that Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) showed no significant stimulation in rabbits at the test dosage of 10μg/time.

Hemolysis test

Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) has no hemolysis or agglutination in direct contact with blood.

Active systemic anaphylaxis test

Guinea pigs were sensitized by intraperitoneal injection of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) at 5 μg/kg and 0.5 μg/kg respectively every other day for 3

consecutive times. On Day 12 after the last sensitization, guinea pigs in the two doses groups were given single intravenous injection with 2 times the sensitization dosage of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) for provocation. Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) showed no anaphylaxis in guinea pigs. The study results indicated that the guinea pigs in two doses groups showed no significantly abnormal reaction during sensitization, and the body weight increased over the test time. The average body weight of guinea pigs when the first sensitization, last sensitization and challenge was similar to that in the negative control group of 0.9% NaCl injection at the corresponding time.

6. Pharmaceutical particulars

6.1 List of excipients

Disodium hydrogen phosphate

Potassium dihydrogen phosphate

Sodium chloride

Phenol

Polysorbate 80

6.2 Incompatibilities

In the absence of compatibility studies, this product must not be mixed with other medicinal products.

6.3 Shelf life

24 months.

This product should be used within half an hour after opening

6.4 Special precautions for storage

Store and transport at 2℃~8℃, keep away from light.

6.5 Nature and content of container

This product is a liquid detection reagent, packaged in vials.

Packaging: 0.3 ml, 0.5 ml, 1.0 ml/vial, 1 vial/box.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer

Name: Anhui Zhifei Longcom Biopharmaceutical Co., Ltd.

Address: No. 100, Fushan Road, High-tech Industrial Development Zone , Hefei City, Anhui Province, China

8. Marketing Authorization Holder

Name: PT Jakarta Biopharmaceutical Industry

Address: Kawasan Industri Modern Cikande, Jalan Modern Industri XV Blok AD No. 3, Desa Sukatani, Kab. Serang, Banten, Indonesia

9. Marketing authorization number

Date of first marketing authorization approval:

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

INFORMASI PRODUK UNTUK PASIEN
C-TST

1. NAMA OBAT

Nama Generik : Recombinant Mycobacterium Tuberculosis Fusion Protein (EC)

Nama Dagang : C-TST

2. BENTUK SEDIAAN

Injeksi

3. PEMERIAN OBAT

Cairan tidak berwarna untuk injeksi.

Produk ini adalah cairan tidak berwarna dan bening, bebas dari zat atau kotoran yang tidak larut.

4. KOMPOSISI ZAT AKTIF DAN KEKUATAN OBAT

Dosis untuk setiap orang adalah 0.1ml, setiap 0.1ml mengandung 5U Rekombinan Mycobacterium Tuberculosis Fusion Protein (EC).

5. INDIKASI

Produk ini diindikasikan untuk diagnosis infeksi Mycobacterium tuberculosis, dan dianjurkan untuk dewasa umur 18 tahun – 65 tahun.

Hasil tes kulit dengan produk ini tidak terpengaruh oleh vaksin Bacillus Calmette-Guérin (BCG) dan sangat cocok untuk diagnosis *auxiliary* tuberkulosis (TB).

6. POSOLOGI DAN CARA PEMBERIAN

Produk ini diberikan sebanyak 0,1 mL sekali pemberian.

Penggunaan produk ini dan interpertasi hasil hanya bisa dilakukan oleh tenaga medis.

Cara Pemberian

Penggunaan produk ini tanpa kombinasi: Ambil 0,1 ml (5 U) produk ini dan suntikkan secara intradermal pada lengan bawah di sisi telapak menggunakan metode Mantoux.

Penggunaan produk ini dikombinasikan dengan TB-PPD: Ambil 0,1 ml (5 U) produk ini dan 0,1 ml (5 IU) TB-PPD, masing-masing, dan suntikkan produk ini secara intradermal pada lengan bawah kiri di sisi telapak menggunakan metode Mantoux. Jika tidak ada kelainan yang diamati setelah 5 menit, kemudiaan suntikkan PPD pada lengan bawa kanan di sisi telapak.

Penentuan Hasil

Penggunaan produk ini tanpa kombinasi: Reaksi di tempat injeksi harus diperiksa 48 ~ 72 jam setelah injeksi, dan diameter melintang dan diameter longitudinal (mm) kemerahan dan indurasi harus diukur dan dicatat, mana yang lebih besar. Reaksi dengan diameter rata-rata (jumlah diameter melintang dan diameter longitudinal dibagi 2) ≥ 5 mm dianggap sebagai reaksi positif. Mereka yang memiliki lepuh, nekrosis dan limfangitis adalah reaksi yang sangat positif.

Penggunaan produk ini dikombinasikan dengan TB-PPD: Periksa reaksi di tempat suntikan kedua lengan 48 ~ 72 jam setelah injeksi. Pilih mana yang lebih besar dari kemerahan intradermal atau indurasi untuk EC, dan indurasi intradermal saja untuk TB-PPD. Ukur dan catat diameter melintang dan memanjang (dalam mm) kemerahan dan indurasi. Diameter rata-rata kemerahan atau indurasi ≥ 5 mm menunjukkan reaksi positif. Mereka yang memiliki lepuh, nekrosis dan limfangitis adalah reaksi yang sangat positif.

Hasil spesifiknya adalah penentuan sebagai berikut:

PPD	EC	Penentuan Hasil
-	-	Tidak ada vaksinasi Bacille Calmette-Guerin (BCG) atau konversi negatif setelah vaksinasi BCG dan tidak ada infeksi dengan Mycobacterium tuberculosis
+	-	Tetap positif setelah vaksinasi BCG
+/-	+	Infeksi Mycobacterium tuberculosis

7. KONTRAINDIKASI

Jangan menggunakan produk ini jika menderita penyakit menular akut (seperti campak, pertusis, influenza, pneumonia, dll.), konjungtivitis okular akut, otitis media akut, penyakit kulit yang luas dan konstitusi alergi.

8. PERINGATAN DAN PERHATIAN

Beritahukan kepada dokter jika ada menderita penyakit berat atau sedang dalam pengobatan penyakit.

Jarum suntik untuk menyuntikkan produk ini tidak boleh digunakan untuk produk lain.

Produk ini tidak boleh digunakan jika botol retak atau ada benda asing di dalam produk.

Produk ini harus digunakan dalam waktu setengah jam setelah dibuka.

9. INTERAKSI OBAT

Aman digunakan bersama dengan TB-PPD sesuai dengan uji klinis .

Tidak ada studi interaksi dengan obat lain selain yang disebutkan di atas

10. KEHAMILAN DAN MENYUSUI

Belum ada data yang dikumpulkan tentang penggunaan produk ini pada wanita hamil dan menyusui.

11. EFEK SAMPING

Sejumlah 3854 subjek terlibat dalam 7 uji klinik yang telah dilakukan. Subjek termasuk pasien dengan tuberculosis, pasien dengan penyakit non-tuberculosis lainnya, subjek sehat, subjek yang baru divaksinasi BCG , dan subjek yang divaksinasi BCG placebo. Sebagian besar studi klinis dirancang bahwa EC dan TB-PPD disuntikkan pada lengan yang berbeda dari tubuh yang sama. Efek samping sistemik adalah data yang diamati ketika produk ini digunakan dalam kombinasi dengan TB-PPD.

Efek samping sistemik yang umum dialami termasuk kesakitan, demam, kelelahan, sakit kepala. Efek samping lokal yang umum dialami adalah gatal/ kesakitan pada tempat penyuntikkan.

	Pasien dengan TB dan penyakit non-tuberkulosis lainnya	Pasien Sehat
Efek Samping Sistemik	Sering: Kesakitan, demam, kelelahan, sakit kepala	Sering: demam
	Tidak Sering: Bradikardia atau takikardia, ruam, petekie, pusing, polipnea, disforia, dan hipersensitivitas.	Tidak Sering: Sakit kepala, mual, kelelahan, mialgia, diare, muntah, parestesia
	Jarang: Rasa terbakar, gatal, dermatitis kontak, nyeri tekan, menggigil, nyeri dada, mulut kering, nyeri orofaring, sensasi demam, nyeri kulit, cedera mata, limfadenitis, dan dermatitis alergi.	Jarang: Rasa tidak nyaman di dada, pusing, nafsu makan menurun, gatal
Efek Samping Lokal	Sangat Sering: Gatal pada tempat penyuntikkan	Sering: Gatal / kesakitan pada tempat penyuntikkan
	Tidak Sering: Nyeri, vaskulitis dan pembengkakan di tempat penyuntikan.	Tidak Sering: Ruam pada tempat penyuntikan
	Jarang: Perdarahan, urtikaria, nekrosis, memar dan perubahan warna pada tempat penyuntikan	Jarang: Pendarahan pada tempat penyuntikan

Hubungi dokter Anda jika Anda mengalami efek samping apapun yang dirasakan setelah penggunaan produk ini, laporkan efek samping ke :

PT Jakarta Biopharmaceutical Industry

Melalui pos : Jl. Musi no. 15, Cideng, Kec. Gambir, Jakarta Pusat 10150

Email : admin@jbio.co.id

Tel: +62-21-50208838

12.KEMASAN

Dus, 1 vial @ 0,3 mL

Dus, 1 vial @ 0,5 mL

Dus, 1 vial @ 1,0 mL

13.CARA PENYIMPANAN

Simpan dan kirim pada suhu +2 - +8°C, lindungi dari cahaya.

Produk ini harus digunakan dalam waktu setengah jam setelah dibuka.

14.NOMOR IJIN EDAR

15.PRODUSEN

Anhui Zhifei Longcom Biopharmaceutical Co., Ltd.

No. 100, Fushan Road, High-tech Industrial Development Zone, Hefei City, Anhui Province, China

16.PENDAFTAR

PT Jakarta Biopharmaceutical Industry

Kawasan Industri Modern Cikande Jalan Modern Industri XV Blok AD No. 3, Desa Sukatani, Banten, Indonesia

HARUS DENGAN RESEP DOKTER