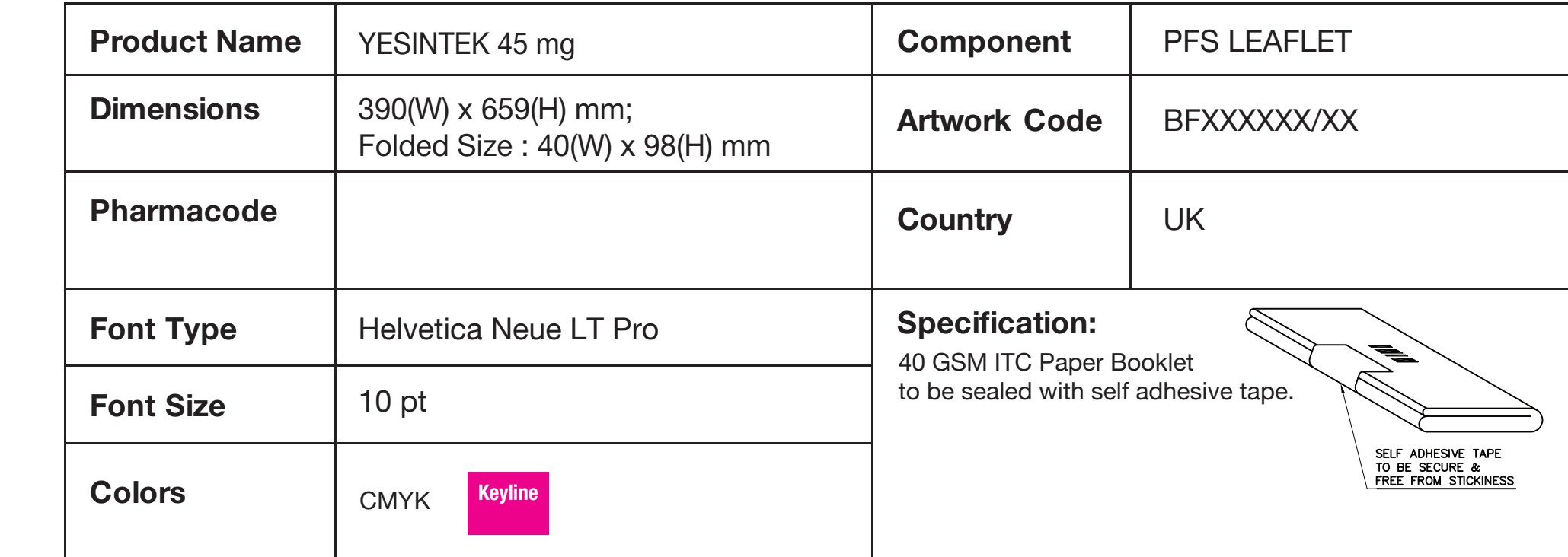




- Drooping eyelid and sagging muscles on one side of the face (‘facial palsy’ or ‘Bell’s palsy’), which is usually temporary
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1 000 people):

- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10 000 people):

- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid)
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Yesintek

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2 °C–8 °C). Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- If needed, individual Yesintek pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the discard date in the space provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature (up to 30 °C), it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake Yesintek pre-filled syringes. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:

- After the expiry date which is stated on the label and the carton after ‘EXP’. The expiry date refers to the last day of that month.
- After discard date recorded on the carton once stored at room temperature, i.e., more than 30 days at 30°C.
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see section 6 ‘What Yesintek looks like and contents of the pack’).
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.

Yesintek is for single use only. Any unused product remaining in the syringe should be thrown away. 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 Yesintek contains

- The active substance is ustekinumab. Each pre-filled syringe contains 45 mg ustekinumab in 0.5 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 (E433), sucrose, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

What Yesintek looks like and contents of the pack

Yesintek is a clear, colorless to pale yellow solution for injection. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled syringe. Each pre-filled syringe contains 45 mg ustekinumab in 0.5 mL of solution for injection.

Marketing Authorisation Holder

Biosimilar Collaborations Ireland Limited

Unit 35/36 Grange Parade, Baldoyle Industrial Estate
Dublin 13, DUBLIN Ireland, D13 R20R

Manufacturers

Biosimilar Collaborations Ireland Limited

Block B, The Crescent Building, Santry Demesne, Dublin
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Biosimilars Newco Limited
Tel: 0080008250910

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