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INFORMATION ON IXEKIZUMAB (TALTZ)

What is IXEKIZUMAB (TALTZ) ?

- This is a medication created by the company Eli Lilly
- Ixekizumab is a humanized IgG4 monoclonal antibody that selectively finds with IL-17 A and inhibits its interaction with the IL17 receptor
- ➤ Ixekizumab is an injection which blocks a pathway inside inflammatory cells known as the IL17A pathway
- > Studies showed that about 80 % of people who take the drug will have their psoriasis improved by about 75 % after 3 months use use and 35 % will have their psoriasis completely cleared up.
- > After one year about 50 % of patients will have clear skin.

Who does IXEKIZUMAB (TALTZ) help?

➤ The drug was formally approved by the FDA in March 2016 for the treatment of adult patients with moderate plaque psoriasis (3-10% surface area) or severe plaque psoriasis (10 % or more surface area) who are candidates for systemic therapy or phototherapy. In another scoring system, a PASI of *more than 10* (out of 72) equates to moderate to severe severity.

Here are some other benefits

- Nail psoriasis. It can be used off label in nail psoriasis. After 60 weeks of treatment, it was found that about 50 % of patients had clear nails
- Scalp psoriasis. After three months of treatment about 75 % of patients reported that their scalp psoriasis had cleared.

If patients did not improve with other biologics like Etanercept (Enbrel), can they still improve with IXEKIZUMAB (TALTZ)?

➤ Yes, about 84 % of patients who failed Enbrel still saw a 75 % improvement in their skin after three months.

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What is the dose of IXEKIZUMAB (TALTZ) ?

- ➤ The dose is 160 mg for the first subcutaneous (SC) injection and then 80 mg SC for the next 12 weeks (6 doses).
- After the 12th week, the dose is 80 mg every 4 weeks.
- > The medication is injected into the upper arms, thigh, buttocks or abdomen in a rotating manner.
- The medicine is stored in the refrigerator. The medicine should be allowed to reach room temperature for at least 30 minutes before taking off cap and injecting

How is IXEKIZUMAB (TALTZ) supplied to me?

- ➤ The medication is supplied in prefilled syringes containing 80 mg of ixekizumab.
- It should come as a clear, colorless to slightly yellow solution
- ➤ The other ingredients in the syringe are sodium chloride, citric acid, polysorbate 80 and water.
- ➤ Each syringe comes with a 27 gauge ½ inch needed.
- Syringes can be ordered as either an auto injector or a syringe.

Who should NOT use IXEKIZUMAB (TALTZ) ?

- > Patients with inflammatory bowel disease
- > Women who are pregnant
- > Patients under 18 or over 65
- Patients with active infection

What are the possible side effects of IXEKIZUMAB (TALTZ) ?

About 85 % of patients experience some type of side effect of ixekizumab. Generally speaking, they are mild and do not lead to stopping the treatment. In clinical trials about 2 % of patients stopped treatment due to side effects compared to 1 % of those using the placebo.

- Generally speaking, side effects often happen in the first few months.
- The most common side effects are cold and upper respiratory tract infections
- Serious adverse events in clinical trials occurs in 11. 8 % of patients.
- ➤ Injection site reactions in 15-20 %
- Respiratory tract infections in 14-17 %

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Side effects of IXEKIZUMAB (TALTZ) - Continued

- > Tinea (fungal infections) in 2 %
- Conjunctivitis and eye infections
- ➤ Nausea in 2 %
- Oropharyngeal pain (1.4 %)
- ➤ Low platelets (3%)
- ➤ Low neutrophils (neutropenia) 2 %
- Anaphylaxis

What tests and procedures will be needed <u>before</u> taking IXEKIZUMAB (TALTZ) ?

- ➤ A TB skin test will be needed
- ➤ Infection screens for Hepatitis C, Hepatitis B, HIV are required
- ➤ Baseline blood tests for: CBC, TSH, ALT, AST, Bilirubin, creatinine, urinalysis, ANA, ESR
- Consider discussing with your family doctor and dermatologist whether shingles vaccines and flu vaccines are appropriate <u>before</u> starting the treatment

What tests and procedures will be needed <u>after</u> starting the IXEKIZUMAB (TALTZ) ?

- > CBC, AST, ALT creatinine, urinalysis at month 1, month 3 and month 6
- > Follow up examinations are needed in the office at month 1, 3, 6 and 12

What precautions are needed in those using IXEKIZUMAB (TALTZ) ?

- Live vaccines should not be used while using this medication
- > Be sure to tell all health care professionals you use this medication, including the dentist.
- Side effects must be reported to the doctor and possibly Health Canada and the FDA

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