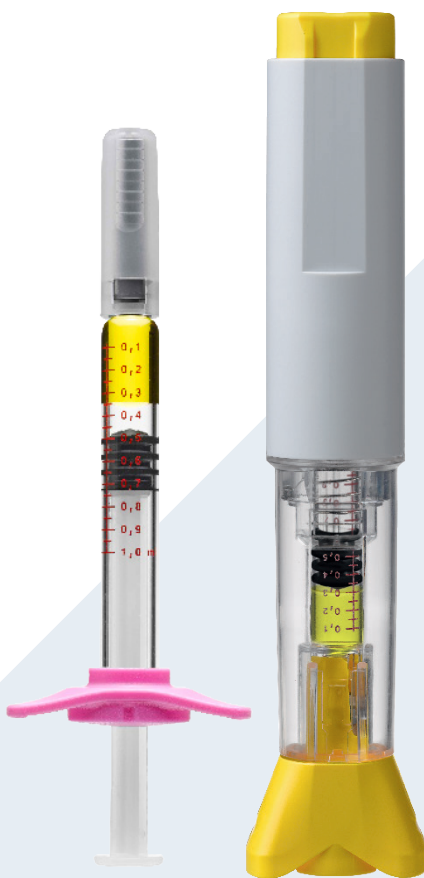

SUBCUTANEOUS METHOTREXATE IMPROVES FATIGUE AND NAUSEA

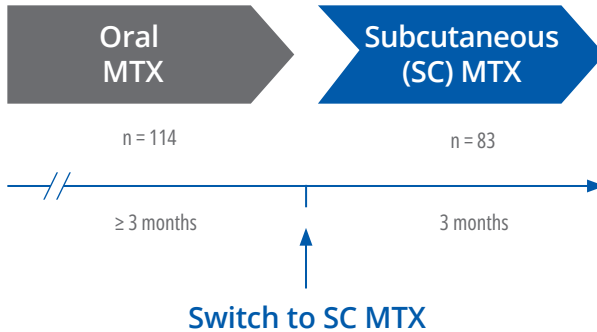
New results from a Danish psoriasis study



medac

STUDY FROM DENMARK EXTENDS BENEFITS OF SUBCUTANEOUS METHOTREXATE SWITCH

PROSPECTIVE MULTI-CENTRE COHORT STUDY DESIGN



- Patients with psoriasis on oral MTX with side effects were asked if the side effects improved when they were switched to the subcutaneous administration. Here, drug-induced nausea and fatigue were measured.
- Patients were older than 18 years and were treated with oral MTX for at least 3 months.
- At time of switching from oral to SC MTX and 3 months later, the patients' symptom frequency and intensity were recorded using the Visual Analogue Scale (VAS, 0–100, 0 = no symptoms, 100 = worst symptoms imaginable).

BASELINE CHARACTERISTICS

Participants	n = 83 (100 %)
Female/male	48.2 %/51.8 %
Mean age (SD)	42.5 y (14.1)

INDICATIONS

Psoriasis	
Skin	77.1 %
Nail	37.3 %
Eczema	14.5 %
Other	9.6 %

TREATMENT

MTX dose before/after switch	15.5/15.1 (mg/week)
Folic acid suppl.	95.2 %

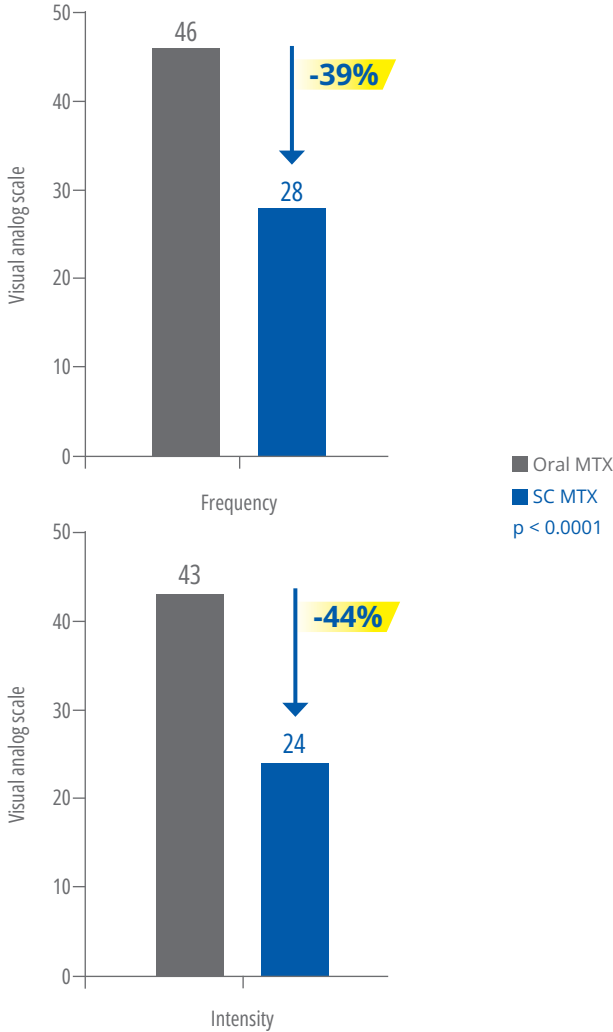
MAJOR REASONS FOR SWITCHING TO SC MTX*

Gastrointestinal	
Nausea	49.4 %
Vomiting	9.6 %
Abdominal pain	22.9 %
Fatigue	39.8 %

* More than one option possible.

OUTCOME: SUBCUTANEOUS METHOTREXATE SWITCH SIGNIFICANTLY REDUCED NAUSEA¹...

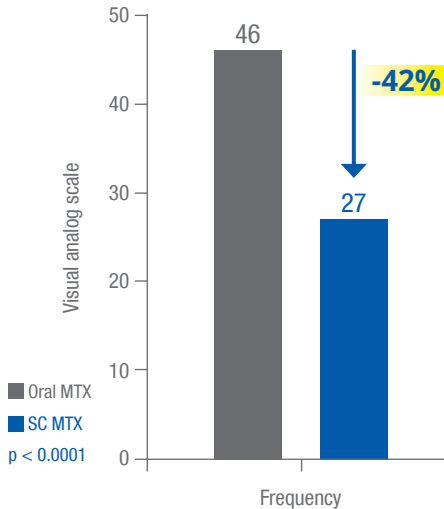
EFFECT ON NAUSEA



NOTE: In a subgroup (n=35) who cited nausea as the main reason for switching, the frequency and intensity of nausea both further significantly improved by $\geq 50\%$ (data not shown).

...AND FATIGUE¹!

EFFECT ON FATIGUE



- The significant improvement of nausea is clinically relevant as the VAS score surpasses the Minimal Clinical Important Difference of 15.
- For fatigue, a similar clinical difference is hypothesized.

Switching to subcutaneous methotrexate significantly improved the frequency of fatigue as well as the frequency and intensity of nausea.

4 out of 5 patients preferred subcutaneous methotrexate!

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(metotreksat)

meto
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(metotrexat)

metex[®] Pen
(methotrexat)

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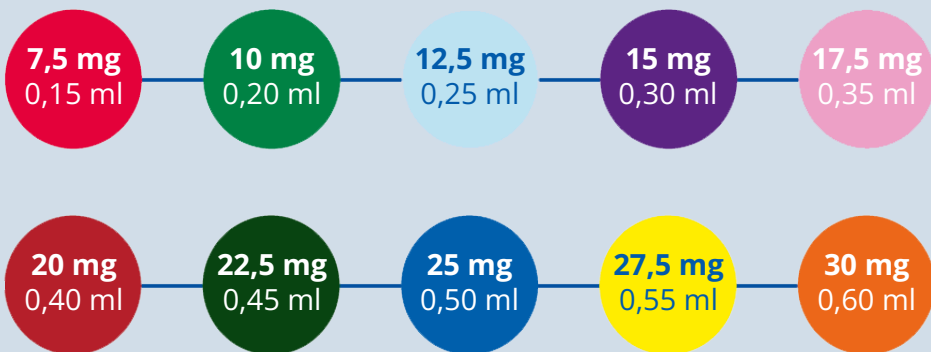
metex[®]
(methotrexat)

BENEFITS OF SUBCUTANEOUS METHOTREXATE IN PSORIASIS THERAPY

Published data from direct comparison between the two application routes clearly favor the therapy with subcutaneous methotrexate in psoriasis:

- ▶ Faster onset of response, increased effectiveness²
- ▶ More stable long-term treatment²
- ▶ Less discontinuation than with MTX tablets²
- ▶ Following switch, improved tolerability¹

UP TO 10 DOSE OPTIONS AVAILABLE FOR INDIVIDUALIZED THERAPY*



* Availability depending on country

¹ Diernæs JEF, Kromann CB, Boel M, et al. JAAD 2021. Published ahead of print. DOI:<https://doi.org/10.1016/j.jaad.2021.12.039>.

² Reich K, Sorbe C, Griese L et al. Br J Dermatol 2020.

Online ahead of print (<https://onlinelibrary.wiley.com/doi/abs/10.1111/bjd.19690?af=R>)

Metoject® PEN / Metex penn® / metex® Pen (methotrexate) solution for injection, pre-filled pen

Metoject® / metex® (methotrexate) 50 mg/ml solution for injection, pre-filled syringe

7.5 mg / 10 mg / 12.5 mg / 15 mg / 17.5 mg / 20 mg / 22.5 mg / 25 mg / 27.5 mg / 30 mg

(all dosages might not be available in every country)

Once weekly, administered subcutaneously

Therapeutic indications: Active rheumatoid arthritis in adult patients; polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate; severe psoriatic arthritis in adult patients; mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines.

Metoject® PEN / Metex penn® / metex® Pen additionally: moderate to severe psoriasis in adult patients who are candidates for systemic therapy. Syringe additionally: severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA and retinoids.

Contraindications: Hypersensitivity to methotrexate or any of the excipients; severe liver impairment; alcohol abuse; severe renal impairment (creatinine clearance < 30 ml/min); pre-existing blood dyscrasias (bone marrow hypoplasia, leukopenia, thrombocytopenia, significant anaemia); serious, acute or chronic infections such as tuberculosis, HIV, other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breastfeeding; concurrent vaccination with live vaccines.

Special warnings and precautions for use: In the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis and psoriatic arthritis, and Crohn's disease, **Metoject® PEN / Metex penn® / metex® Pen** (methotrexate) must only be used once a week. Dosage errors in the use can result in serious adverse reactions, including death.

ATC-code: L04AX03 **Legal classification:** POM

Marketing authorisation holder: medac GmbH, Theaterstr. 6, 22880 Wedel, Germany.

Date of revision of text: 2022-03-17

SE: Read more at www.fass.se

NO: Read more at www.felleskatalogen.no

DK: Read more at www.medicin.dk

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