

## Press release

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# **metex<sup>®</sup>/metoject<sup>®</sup> PEN – first marketing authorisation worldwide for methotrexate in moderate psoriasis**

**Medac's marketing authorisation extension gives many patients with psoriasis access to guidelines-based MTX therapy for the first time**

- Over a third of all patients with moderate psoriasis<sup>1</sup> have to date not had officially approved access to first-line therapy with methotrexate
- Since April 2018, the metex<sup>®</sup>/metoject<sup>®</sup> PEN<sup>2</sup> has Europe-wide marketing authorisation for the treatment of moderate psoriasis, in addition to the treatment of severe forms
- Long-term data demonstrate a rapid onset of action and good, lasting efficacy of subcutaneous MTX in moderate psoriasis
- A simple treatment regimen (once a week) and user-friendly, safe handling with the metex<sup>®</sup>/metoject<sup>®</sup> PEN promote treatment compliance

*Wedel (April 13 2018).* Medac has announced that, with the metex<sup>®</sup>/metoject<sup>®</sup> PEN, methotrexate (MTX) has been authorised by the authorities for the systemic treatment of moderate to severe psoriasis for the first time.

Methotrexate is the most commonly used systemic medicine for the treatment of psoriasis worldwide and is recommended as a first-line systemic therapeutic agent by the current guidelines.<sup>3,4,5</sup> This

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<sup>1</sup> Yeung H et al. JAMA Dermatol. 2013;149(10):1173-9.

<sup>2</sup> Equivalent to metojectpen<sup>®</sup> and Rasuvo<sup>™</sup>

<sup>3</sup> Nast A et al. J Eur Acad Dermatol Venereol. 2015;29:2277-94.

<sup>4</sup> Association of the Scientific Medical Sciences in Germany (AWMF): Nast A et al. S3 - Guideline on the treatment of psoriasis vulgaris Update 2017 [in German]. URL: [http://www.awmf.org/uploads/tx\\_szleitlinien/013-0011\\_S3\\_Therapie\\_Psoriasis-vulgaris\\_2017-12.pdf](http://www.awmf.org/uploads/tx_szleitlinien/013-0011_S3_Therapie_Psoriasis-vulgaris_2017-12.pdf) (11.04.2018).

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applies to both severe and moderate psoriasis, with parenteral administration being preferred. However, the use of MTX in the treatment of moderate psoriasis has to date only been “well-established off-label use” because this indication was not approved anywhere in the world.

Medac’s initiative now means that, for the first time, over a third of psoriasis patients<sup>6</sup> will have an effective treatment option with the established drug methotrexate in the effective and user-friendly subcutaneous (SC) form of administration as an autoinjector.

### **METOP study<sup>7</sup> proves effectiveness and safety of SC MTX in moderate psoriasis**

Apart from the data of a large German register<sup>8</sup>, a subgroup analysis of the Methotrexate Optimized treatment schedule in patients with Psoriasis (METOP) study<sup>9</sup> published in *The Lancet* in 2017 confirms the good results in terms of effectiveness and safety of subcutaneous administration of MTX in a direct comparison of severe and moderate forms of psoriasis (Figure 1). After just 16 weeks, the analysis showed that the psoriasis area severity index (PASI) in the severe forms<sup>10</sup> had fallen from 25 to 6 and in the moderate forms from 14 to 4.5. After 52 weeks, the PASI scores were just 3.2 and 2.4, respectively. The study showed that subcutaneous methotrexate is characterised by a rapid onset of action in both severe and moderate forms and, moreover, it has a comparable effect and long-lasting efficacy.

<sup>5</sup> Warren RB et al. *Br J Dermatol*. 2016;175:23-44.

<sup>6</sup> Yeung H et al. *JAMA Dermatol*. 2013;149:1173-79.

<sup>7</sup> Warren RB et al. *Lancet*. 2017;389:528-37.

<sup>8</sup> Augustin A et al. *J Dtsch Dermatol Ges*. 2014;12(1):48-57.

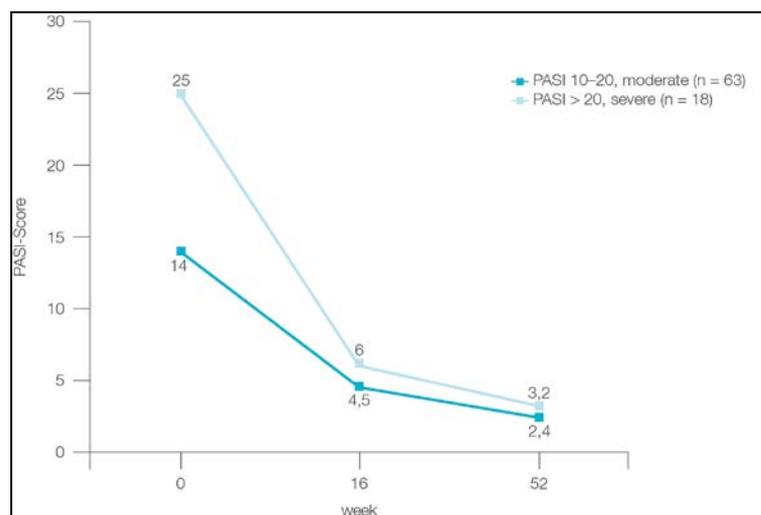
<sup>9</sup> ClinicalTrials.gov: Trial in Patients With Psoriasis Treated With Methotrexate Using an Optimized Treatment Schedule (METOP). <https://clinicaltrials.gov/ct2/show/NCT02902861> (11.04.2018).

<sup>10</sup> A PASI of 10-20 is considered moderate and a PASI >20 severe, according to, inter alia, Augustin M et al. *Dermatology*. 2008;216:366-72; Reich K et al. *JDDG*. 2009;7:603-10.

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**Figure 1:** The change in the PASI over time shows a rapid onset of action and comparable efficacy of subcutaneous MTX in moderate and severe psoriasis.<sup>11</sup> © medac

### Methotrexate in psoriasis therapy: effective, safe and cost-effective

In addition to its safety and efficacy, methotrexate has also been shown to be cost-effective in various studies,<sup>12,13</sup> most recently in a cost model by Medac.<sup>14</sup> This model showed superior cost-effectiveness of treatment with methotrexate in moderate to severe plaque psoriasis. The metex<sup>®</sup>/metoject<sup>®</sup> PEN is thus currently the most economic licensed systemic therapy for the management of psoriasis.

### Methotrexate from Medac – always one step ahead

With the introduction of the autoinjector in Germany at the start of 2013, Medac made methotrexate commercially available in the pharmaceutical form of a ready-to-use pen for the very first time anywhere in the world. The metex<sup>®</sup>/metoject<sup>®</sup> PEN<sup>15</sup> is now the most frequently used therapeutic

<sup>11</sup> Internal subgroup analysis based on the METOP study

<sup>12</sup> D'Souza LS, Payette MJ. *J Am Acad Dermatol.* 2015;72:589-98.

<sup>13</sup> Roldán FA. *Rev Esp Salud Pública.* 2016;90:1-7.

<sup>14</sup> Bungey G et al. *Value in Health.* 2017;20:A549–A50.

<sup>15</sup> The autoinjector is now also available in other countries, including the UK, Scandinavia, France, the USA and Spain.

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agent for parenteral MTX in Germany.<sup>16</sup> User-friendly operation is probably one reason for this. The autoinjector makes subcutaneous self-administration of MTX a simple and safe process. A Medac survey documenting practices among German rheumatologists and patients with rheumatic disease confirms: “97% of all doctors and 89% of patients with previous experience of ready-to-use syringes rated the metex<sup>®</sup> PEN as ‘very advantageous’ or ‘advantageous’ compared with a ready-to-use syringe.”<sup>17</sup> Numerous publications show that this encourages patient compliance with treatment.<sup>18,19,20</sup>

In mid-2013, Medac closed an important gap between actual treatment practices and regulatory oversight of medicines with the first authorised indication for methotrexate in gastroenterology anywhere in the world.

With the METOP study and now the Europe-wide extension of the marketing authorisation for the metex<sup>®</sup>/metoject<sup>®</sup> PEN to also include moderate psoriasis, Medac has once again succeeded in bridging the gap between actual medical practice and efficacy and safety of subcutaneous methotrexate confirmed at regulatory level.

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<sup>16</sup> Insight Health. Nationaler Pharmaindex (NPI), Q1 2018.

<sup>17</sup> Hattesoehl M. et al. Handhabung eines Fertigpen zur subkutanen Selbstapplikation von Methotrexat [Handling of a ready-to-use pen for subcutaneous self-administration of methotrexate]. Germany Society of Rheumatology (DGRh) Abstract 2017. URL: <http://www.egms.de/static/de/meetings/dgrh2017/17dgrh244.shtml> (11.04.2018).

<sup>18</sup> Demary W et al. Patient Prefer Adherence. 2014;8:1061-71.

<sup>19</sup> Pachon JA et al. SAGE Open Med. 2014;2:2050312114564241.

<sup>20</sup> Pichlmeier U, Heuer KU. Clin Exp Rheumatol. 2014;32:563-71.

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### medac Gesellschaft für klinische Spezialpräparate mbH

medac is a privately held German pharmaceutical company located near Hamburg in Wedel and Tornesch. Medicinal products from medac support doctors and patients throughout the world in overcoming their acute and persistent diseases in the indication areas of oncology & haematology, urology and autoimmune disorders. In addition, medac develops and markets special diagnostic test systems. Since 1970, medac has been committed to unifying therapeutic and diagnostic agents under one roof.

You can find further information on the company and its products on the internet under [www.medac.de](http://www.medac.de).