

Early Access Program

Irminix[®]

(INN: *Emeramide* – Code: *NBMI*)

Warning: Do not acquire
and use a counterfeit,
Chinese made product.
More info on
www.emermed.com

Dear Patient or Physician: Before emailing questions, please first fill in and send us the basic patient information below. And please read and follow the steps described on the next page.

Drugs under development can be approved for use by a regulatory authority on an *Individual Patient Use* basis. This is also called Expanded Access, Named Patient Use, or Compassionate Use, depending on the country. The approval is based on whether the condition to be treated is serious enough, whether efficient and safe treatments are existing or lacking, and whether the drug has shown relevant efficacy and safety. The physician is responsible for the treatment. In most countries, **only a licensed physician can apply to the regulatory authority**. To date, we have experience with approvals and shipping to Switzerland, Germany, Austria, New Zealand, Lebanon and the USA. Most US patients and physicians find the FDA process too complicated and instead go to Germany or NZ.

Currently, we can offer a 14-day treatment x 300mg per day. The treatment length and dosing are determined by the length of the Phase 1 and 2a clinical studies that have been performed. If this is enough depends on the individual patient – some require several treatments, typically with 28 days in between. There is no charge for the drug, but a cost of €600 (\$750) for insurance-Shipping-Administration per two-week-treatment.

No approval by the regulatory authority needed for the physician to order the drug:

- **New Zealand:** <http://www.medsafe.govt.nz/profs/riss/unapp.asp>
- **Lebanon:** Ministry of Public Health approved the import of Irminix for Individual Patient use.

Approval by the regulatory authority not required under certain circumstances:

- **Austria:** Named Patient Use
http://www.basg.gv.at/fileadmin/user_upload/L_1236_Information_Named_Patient_Use_en.pdf
- **Germany:** The physician contacts the regulatory authority BFARM.

Approval from regulatory authority required in most countries:

- **Switzerland:** *Sonderbewilligung*. We provide the application filled in.
- **Sweden:** *License* <https://lakemedelsverket.se/licens>
- **Denmark:** *Compassionate Use to named patient*
<https://sundhedsstyrelsen.dk/en/medicines/regulation/compassionate-use-permits>
- **UK:** *Individual Patient use, Specials*. A company needs to import the drug for the physician; the physician contacts earlyaccess@emeramed.com.
www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials_.pdf
- **Australia:** *Special Access Scheme* <https://www.tga.gov.au/form/special-access-scheme>
- **Canada:** *Special Access Program* <http://www.hc-sc.gc.ca/dhp-mpps/acces/drugs-droques/index-eng.php>
- **US:** *Individual Patient IND under Expanded Access for Non-emergency or Emergency Use*. Note that this is a complicated process that demands some five documents to be submitted to the FDA and, that after FDA approval, an Institutional Review Board (IRB) is required to oversee the actual treatment. More details at www.emeramed.com/earlyaccess
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm>
- **And most other countries**

How to obtain *Irminix*[®] & Prescription

1a. Email the below info to earlyaccess@EmeraMed.com. Filled in by Patient or Physician.

*Date of Request (DD/MMM/YYYY):	Click here to enter a date.
Patient	
*Name:	<enter first and last name>
* Address:	
* Zip code & City	
* Country:	
*E-mail:	
*Age:	
*Briefly describe the disease/indication intended to be treated. Patient medical history/current physical condition, summary of any relevant tests done with dates & rationale for request to use Irminix:	
* Briefly describe previous use of metal chelators (such as DMPS, DMSA, BAL, EDTA and OSR#1). When were they used? How much was taken per day and how long? What were the results on health and on metal tests and other tests?	
* Briefly describe current treatments, medications, including herbals and other dietary supplements.	

1b. Prescription (If there is yet no physician, leave blank. It will need to be signed later on.)

Physician	
*Name:	
* Address:	
* Zip code	
* Country:	
*E-mail:	
*Tel:	
<i>Shipping address if other than the above – we can only ship to physician, clinic or pharmacy, not to patient</i>	
<i>Address for shipping:</i>	
<i>Zip code & City</i>	
<i>Country:</i>	
<i>Number of treatments prescribed</i>	
<i>Number of treatments (each 14 days x 3 capsules of 100mg)</i>	

Physician's signature

2. If accepted by the Company, the physician will be provided with documents to send to the regulatory authority.

3. Physician applies to the regulatory authority (if required, see previous page).

4. Physician sends the following documents in one email to EarlyAccess@EmeraMed.com:

- A. *Prescription* (this is this document, with signature above)
- B. *Approval* from the regulatory authority (if required; see previous page) *in English* (or the original + a translation to English)

- C. *Physician's license*, copy as PDF
- D. *Informed consent* form signed by physician and patient

5. The drug is dispatched to the physician. An invoice is emailed to the physician – there is no charge for the drug, but a cost of €600 (\$750) for insurance-Shipping-Administration.

6. 1-3 months after treatment, please fill in the After-treatment-report form on the next page and send to EarlyAccess@EmeraMed.com. The patient may send this in, unless that there have been adverse events which the physician reports.