SUBSCRIBE NO to Prescrire International

| Subscription rates | 1 year | 2 years |
|---------------------------|--------|---------|
| Individual rate (1) | €130 | €240 |
| Student rate (1) | €60 | €112 |
| Institutional rate (1)(2) | €325 | €630 |

¹⁻ For Solidarity subscription rates see the preceding page.

| 2- | Commercial | companies | and | institutions. |
|----|------------|-----------|-----|---------------|
|----|------------|-----------|-----|---------------|

| Yes, I would like to subscribe to Prescrire International |
|--|
| Please send me a free sample issue of the French journal <i>Prescrire</i> |
| Title: Mr Ms |
| Last Name: |
| First Name: |
| Address (1): |
| |
| Postal code: City: |
| Country: |
| Tel: |
| Fax: |
| E-Mail (must be provided): |
| |
| Occupation: |
| working in the community, hospital, university, industry other (please circle) |
| 1- Give the format of the address as it is used in your country. |
| ☐ I enclose a cheque for € |
| I pay €by Credit card |
| Visa Eurocard/mastercard American Express |
| Card number: Lilian Expiry date: Lilian Expiry |
| Signature: |

Postage and handling charges are included in the quoted prices. Subscribers outside the European Union who are subject to value added tax (VAT) may pay the ex-tax cost: divide the full cost by 1.021. EU subscribers subject to VAT must provide us with their VAT code number.

Send your order with payment to:

Prescrire International 83 bd Voltaire - 75558 PARIS CEDEX 11 -**FRANCE**

Fax: + 33 1 49237648 e-mail: international@prescrire.org website: english.prescrire.org

Fingolimod (Gilenya°): EMA's lack of transparency spells danger for patients

The European Medicines Agency (EMA) refused to supply Prescrire with data on cases of death following the first dose of fingolimod (Gilenya°). Below are a summary of the press release issued by Prescrire on 20 February 2012, and an update detailing EMA'S latest refusal.

- Fingolimod (Gilenya°) is an immunosuppressant authorised since March 2011 by the European Medicines Agency (EMA) for certain patients with multiple sclerosis.
- The pre-marketing evaluation data already revealed cardiac arrhythmia, among other disorders. In April 2011 Prescrire recommended limiting use of fingolimod to rigorously supervised clinical trials.
- In December 2011, the US Food and Drug Administration (FDA) reported the sudden death of a patient within the first 24 hours of taking fingolimod.
- On 22 December 2011, in response to the FDA alert and faced with the EMA's silence, Prescrire asked the EMA for a review of the serious adverse effects of fingolimod and for the initial European Periodic Safety Update Report (PSUR).
- On 23 January 2012 EMA informed *Prescrire* that its request for information dated 22 December was rejected, on the grounds that a European re-evaluation of fingolimod was under way: the re-evaluation had been initiated 3 days earlier.
- On 7 February 2012, Prescrire reiterated its information request, this time to the EMA Director Guido Rasi.
- Once again the European Agency is refusing to provide patients and healthcare professionals with important information on adverse effects. They give the benefit of the doubt to drug companies rather than to patients, and dispense information about adverse effects only sparingly.
- It is high time that the EMA get back to its primary mission: protecting patients' health, which should take precedence over protecting the financial interests of pharmaceutical companies.
- UPDATE: on 27 February EMA's Director reiterated the Agency's rejection of Prescrire's request for information on fingolimod.

Prescrire

Further details online at **english.prescrire.org** and this issue page 99 Downloaded from english.prescrire.org on 19/12/2025

Copyright(c)Prescrire. For personal use only.