Translated from ***Rev Prescrire*** **February 2015; 35 (376): 94-95**

simeprevir (OLYSIO°)

Chronic hepatitis C: an option for some patients

Abstract

● The choice of treatment for patients with chronic hepatitis C depends on the viral genotype and clinical situation. *Simeprevir* (Olysio°, Janssen Cilag) inhibits the viral protease of hepatitis C virus (HCV) genotypes 1 and 4. *Simeprevir* has been authorised in the European Union for use in combination with other antivirals in adults with chronic hepatitis C.

● In HCV genotype 1 infection, two trials in treatment-naive patients and two trials in patients in whom the *peginterferon alfa* and *ribavirin* combination had failed or who had relapsed showed that virological efficacy was enhanced when *simeprevir* was added to the *peginterferon alfa* and *ribavirin* combination. *Simeprevir* was less effective when the viral protease NS3 carried the Q80K substitution.

● An indirect comparison of the available data suggests that *simeprevir* has about the same virological efficacy as *sofosbuvir* and *boceprevir*, while a trial reported in a conference abstract suggests that it is "non-inferior" to *telaprevir*.

● Results of trials evaluating *simeprevir* without *peginterferon alfa* should be available in 2015. *Simeprevir* has not been evaluated in patients in whom triple-drug therapy has failed. Cross-resistance is likely between *simeprevir* and other viral protease inhibitors. There are no controlled trials of *simeprevir* in patients with HCV genotype 4 infection.

● The main known adverse effects of *simeprevir* are skin reactions (including rash and pruritus), photosensitivity, bilirubin elevation, nausea and dyspnoea. These adverse effects can be severe and even fatal. An increased risk of infections is also likely. *Simeprevir* is a substrate of P-glycoprotein and other transport proteins, as well as of cytochrome P450 isoenzyme CYP3A4, creating a risk of multiple drug interactions. *Simeprevir* bioavailability seems to be higher in patients of Asian origin, exposing them to more adverse effects and warranting the use of a lower dose.

● Simeprevir is taken for 12 weeks, one tablet a day. The daily number of tablets is the same as with *sofosbuvir* and smaller than with *boceprevir* and *telaprevir*.

● In practice, when triple-drug therapy is considered for chronic hepatitis C due to HCV genotype 1 but *sofosbuvir* cannot be used, *simeprevir* seems preferable to other viral protease inhibitors when the virus does not harbour the Q80K substitution. Evaluation of *simeprevir* must continue in patients in whom triple-drug therapy has failed and in patients with HCV genotype 4 infection.

Full review available on request to subscribers. 7 pages, 24 references

POSSIBLY HELPFUL

***Simeprevir* is active in patients with hepatitis C due to genotype I strains lacking the Q80K substitution. When triple-agent therapy is warranted but *sofosbuvir* cannot be used, adding *simeprevir* to the *peginterferon alfa-ribavirin* combination increases the chances of achieving a sustained virological response. *Simeprevir* is slightly better tolerated than *boceprevir* and *telaprevir*. The efficacy of *simeprevir* on other genotypes was not known in late 2014.**

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simeprevir capsules

OLYSIO°

• *Simeprevir* **150 mg** per capsule

HCV antiviral; viral protease inhibitor

■ **Indication:** "*In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients*". [EU centralised procedure]

In response to our request for information, Janssen Cilag provided us with administrative and published data, along with packaging items.

A drug's real name — INN INTERNATIONAL NONPROPRIETARY NAME

COMMON STEM -pamide

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According to the nomenclature used to develop international nonproprietary names (INNs), established by the World Health Organization (WHO), the INNs of diuretics derived from *sulfamoylbenzoic acid* end in the common stem **-pamide** (1,2).

On 12 November 2014, the WHO list of INNs included 6 drugs of this type (1,3). Two of them are marketed in France for the treatment of hypertension: *clopamide* in a fixed-dose combination with *pindolol*; and *indapamide* used alone and in a fixed-dose combination with *perindopril* or *amlodipine* (1,3).

Note that the suffix "mide", which is not on the WHO list of common stems, is also found in the INNs of several other drugs used in various situations (1). For example: *furosemide*, a diuretic, the sulfonylurea *glibenclamide*, the cytotoxic drug *ifosfamide*, and *lenalidomide*, a teratogenic immunosuppressant.

Selected references from Prescrire's literature search.

1- World Health Organization "The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances WHO/EMP/RHT/TSN/ 2013.1": 135.

2- Prescrire Rédaction "Le suffixe du mois: -pamide" *Rev Prescrire* 1990; **10** (102): 511.

3- "Substance names ending with pamide", mednet.who.int accessed 12 November 2014: 1 page.