Translated from ***Rev Prescrire*** **September 2011; 31 (335): 654**

bleomycin in malignant pleural effusion

NEW INDICATION

Choose talc pleurodesis

● **Not more effective than *talc* in preventing recurrent pleural effusions, based on a review with meta-analysis of 7 trials in 256 patients. *Bleomycin* carries a risk of systemic adverse effects and treatment errors.**



NOTHING NEW

Some cancer patients develop malignant pleural effusion that persists or recurs despite cytotoxic chemotherapy and drainage. Pleurodesis using a sclerosing agent instilled into the pleural cavity prolongs the effect of drainage. There is no consensus on the choice of sclerosant, but *talc* is often the first option as it is effective in more than 80% of patients and has few adverse effects.

In France, the indications for Bléomycine Teva° (Teva Santé) have been extended to cover intrapleural treatment of malignant pleural effusion. Does *bleomycin* provide a therapeutic advantage over *talc*?

Not more effective than talc. According to a meta-analysis of 7 comparative randomised trials in a total of 256 patients, *bleomycin* is not more effective than *talc* in preventing recurrent symptomatic or radiological pleural effusion (1). Mortality was not different among the two groups (2,3).

Systemic adverse effects, especially in case of renal failure. A Cochrane review showed that gastrointestinal adverse effects occurred in 17% of patients treated with *bleomycin* but in none treated with *talc*. Other adverse effects were similarly frequent with the two treatments; they mainly consisted of fever and pain, and occasional infectious and cardiopulmonary complications (2,3).

About 45% of the *bleomycin* infused into the pleural cavity enters the bloodstream (4,5), thus exposing patients to the systemic adverse effects of *bleomycin*, such as mucosal and cutaneous lesions, pulmonary disorders (including potentially life-threatening interstitial pneumonia), cardiovascular disorders, and severe anaphylactic reactions (4,5).

As *bleomycin* is mainly eliminated unchanged in urine, the dose should be reduced in case of renal failure (4,5).

Risk of dosing errors. *Bleomycin* dose strength is expressed in several different ways. A dose of 15 000 IU in the European Pharmacopoeia is equivalent to 15 U in the US Pharmacopeia, and to 15 mg of *bleomycin* (4,5). The summary of product characteristics for *Bléomycin* Teva° states that the dose regimen should be expressed in international units (IU), but some hospital protocols use milligrams, which represents a potential source of error (5).

Unlike *talc,* handling of *bleomycin*, a cytotoxic drug, requires the nursing staff to take precautions to avoid accidental exposure (5).

In practice. For cancer patients with persistent or recurrent malignant pleural effusion, it is better to choose *talc* rather than *bleomycin* for pleurodesis, as it is safer and no less effective.

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Selected references from Prescrire's literature search.

In response to our request for information, Teva Health provided us with thorough and relevant material on its product.

1- Tan C et al. "The evidence on the effectiveness of management for malignant pleural effusions: a systematic review" *Eur J Cardiothorac Surg* 2006; **29**: 829-838.
2- Shaw PHS and Agarwal R "Pleurodesis for malignant pleural effusions (Cochrane Review) (last update: 2003). In: "The Cochrane Library" John Wiley and Sons, Chichester 2010; issue 9: 54 pages.
3- Haddad FJ et al. "Pleurodesis in patients with malignant pleural effusions: talc slurry or bleomycin? Results of a prospective randomized trial" *World J Surg* 2004; **28**: 749-753 + invited commentary: 753-754.
4- "Bleomycin sulfate". In: "Martindale The Complete Drug Reference" The Pharmaceutical Press, London. www.medicinescomplete.com accessed 16 June 2011: 16 pages.
5- Afssaps "Résumé des caractéristiques du produit – Bléomycine Teva" 29 April 2010: 10 pages.

bleomycin

BLÉOMYCINE TEVA°

Powder for solution for injection

• **15 000 IU** of *bleomycin* sulphate per 10-ml vial

cytotoxic agent

■ **New indication:**
"intrapleural therapy of malignant pleural effusion".
[French marketing authorisation, European decentralised procedure]

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Measurement units matter

First, do no harm. Patient safety is of constant concern to healthcare professionals. This is why it is better to think, prescribe and speak using the international nonproprietary name (INN), "a drug's real name". In practice, especially when writing prescriptions, the INN should be accompanied by the pharmaceutical form, dose strength and dose regimen.

There are several technical obstacles to writing prescriptions using the INN, including the lack of standardised units for expressing the amount of drug to be administered. In the absence of a universally accepted definition, units of *botulinum toxin* vary from one commercial product to another: the Allergan units chosen for Botox° do not correspond to the Speywood units used for Dysport°; yet both products contain *botulinum toxin type A* (see page 287).

In the case of *bleomycin*, 1000 IU in the European Pharmacopoeia is equivalent to 1 U in the US Pharmacopeia and to 1 mg of the drug (Bléomycin Teva°, see above). When switching from one system to another, it is crucial to be perfectly clear as to the chosen measurement units.

Patients would be better protected and healthcare professionals' task facilitated if, before a drug is granted marketing authorisation, the regulatory authorities ensured that the proposed dose units do not create a risk of error or confusion with products already on the market.

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