

Vitamin B12 induced acneiform dermatitis

Introduction

Several preparations for Vitamin B12 (hydroxycobalamin, cyanobalamin) suppletion therapy (Neurobion[®], Soluvit[®]), are available in the Netherlands. SPCs mention only hypersensitivity reactions as ADR [1,2]. The Netherlands Pharmacovigilance Centre (Lareb) received reports of acneiform dermatitis.

Reports

Until 15 September 2005, Lareb received 32 reports on vitamin B12 suppletion. Five of these reports concerned acneiform dermatitis – which covers the following MedDRA lower level terms, rash acneiform, dermatitis acneiform, rash acneiform, dermatitis acneiform, and acneiform eruption - (table 1). All patients received vitamin B12 by injections.

Patient A was treated with monthly vitamin B12 injections and developed facial acneiform eruptions 13 days after the first injection. These symptoms were recognised and had occurred four years earlier also after vitamin B12 suppletion. Symptoms had resolved then after cessation.

Patient B had several complaints but acneiform dermatitis was recognised as a reaction similar to previous vitamin B12 injections. He perceived the complaints 10 days after start (three days after the second dose).

Patients C and D did not mention previous experiences or rechallenge. Patient E recovered after cessation.

Table 1. Reports of acneiform dermatitis associated with the use of vitamin B12 injections.

Patient, Sex, age	Drug Indication for use	Concomitant medication	Adverse drug reaction	Time to onset, outcome	remarks
A F, 33	100 µg im monthly vitamin B12 deficiency	vitamin D, metronidazol	acneiform dermatitis'	13 days	same reaction occurred 4 years before
B M, 38	1 mg im once weekly vitamin B12 deficiency	none	acneiform dermatitis, ear pain, headache, dizziness	10 days recovered	acneiform reaction had occurred before
C F, 15	1 mg im	ferrofumarate, folic acid/iron	acneiform dermatitis face	2 weeks	unknown
D F, 27	1 mg im once weekly fatigue	atenolol, levothyroxine, fluticasone, levocetirizine, montelukast	acneiform eruptions	?	unknown
E F, 66	500 µg monthly	?	severe rash head and neck, eruptions	2 months	recovered after cessation

Other sources of information

Literature

Several case reports can be found in literature concerning acne like eruptions and systemic vitamin B12 or vitamin B6 and B12 suppletions [3-4]. The type of acne induced by vitamin B12 deserves a special place among acneiform eruptions. The eruption is monomorphic and of a particular type. It consists of voluminous follicular lesions which develop acutely

after the first injections of vitamin B12 and disappear rapidly when treatment is discontinued [4]. Other descriptions include acneiform rosacea, acneiform rash, and rosacea fulminans. Women seem to be almost exclusively affected [3,6].

Databases

The association of vitamin B12 and acneiform dermatitis is with 5 cases disproportionately present in the Lareb database (ROR 91.7 95% CI 34.6 - 243).

No reliable numbers of disproportionality of acneiform dermatitis and vitamin B12 could be computed from the database of the Uppsala Monitoring Centre of the WHO contains due to the low number of reports and the non-specificity in the coding of the (multi)vitamin B preparations.

Mechanism

The aetiology of acneiform dermatitis resembling rosacea triggered by vitamin B12 or B6 is unknown. Jansen *et al.* suggest that prolonged and increased excretion of the causative substances might cause an irritation of the follicular epithelium and subsequently produces an inflammatory reaction [6].

Conclusion

Lareb has received 5 reports of acneiform dermatitis after intramuscular vitamin B12 suppletion. This association is supported by several case reports in literature and by disproportionality analysis in the Lareb database. This reaction is not mentioned in the SPCs of several vitamin B12 preparations.

References

1. Dutch SPC Neurobion®. (version date 24-6-05) <http://www.cbg-meb.nl/IB-teksten/00531.pdf>
2. Dutch SPC Soluvit® (version date 12-05-05) <http://www.cbg-meb.nl/IB-teksten/09077.pdf>
3. Braun-Falco O, Lincke H. [The problem of vitamin B6/B12 acne. A contribution on acne medicamentosa (author's transl)]. *MMW.Munch.Med Wochenschr.* 1976;118(6):155-60.
4. Dupre A, Albarel N, Bonafe JL, Christol B, Lassere J. Vitamin B-12 induced acnes. *Cutis* 1979;24(2):210-1.
5. Sherertz EF. Acneiform eruption due to "megadose" vitamins B6 and B12. *Cutis* 1991;48(2):119-20.
6. Jansen T, Romiti R, Kreuter A, Altmeyer P. Rosacea fulminans triggered by high-dose vitamins B6 and B12. *Journal of the European Academy of Dermatology and Venereology* 2001;15(5):484-5.