As we have just seen, the minimum toxic dose of aluminum, in humans, both orally, for gastric antacid drugs, and IM, for vaccines, can be obtained by extrapolation from the data. preclinical toxicology in animals. There is no point in making this extrapolation, since, as we have just seen, a drug toxic to animals cannot be administered to humans.

Indeed, it is enough, to be persuaded of it, to carry out this extrapolation, and to evaluate correctly, contrary to what was done by the 4 incompetent experts of the National academy of medicine (Pierre BÉGUÉ, Marc GIRARD, Hervé BAZIN, Jean-François BACH - Vaccine adjuvants: what's new in 2012? Bull. Acad. Natle Méd., 2012, 196, n ° 6, 1177-1181, session of June 26, 2012), the toxicity resulting from the value of the minimum toxic dose of aluminum by the oral route, i.e. 1 mg of aluminum / kg of weight / day.

We see that all the vaccines and gastric antacid dressings containing aluminum are administered in toxic, deadly doses in adults, and, a fortiori, in children; which is strictly prohibited.

To determine the levels of toxicity resulting from the presence of aluminum in gastric antacid dressings, given orally, and in vaccines containing aluminum adjuvants, it is necessary to calculate the amounts of aluminum metal, or more exactly, which comes to the same thing, of  $AI^{3+}$  ion, the only soluble form of aluminum that can circulate in biological media, of the main gastric antacid dressings, marketed in France, as well as those of vaccines containing the aluminum adjuvant.

The Toxic minimum Doses are expressed in aluminum metal, or what amounts quantitatively to the same, in  $Al^{3+}$  ion. In the human body, aluminum can only circulate in the form of  $Al^{3+}$ ion, which is soluble in biological media, unlike aluminum in metallic form, which is completely insoluble in biological media. But quantitatively, the mass of  $Al^{3+}$  is identical to that of Al, i.e. 27. So to calculate the quantities of aluminum metal, that is to say of the ion  $Al^{3+}$ , contained in aluminum hydroxide Al (OH)<sub>3</sub> or aluminum phosphate Al PO<sub>4</sub>, proceed as follows: knowing that the atomic mass of aluminum Al, or of ion  $Al^{3+}$ , is equal to 27, and that the mass of aluminum hydroxide Al (OH)<sub>3</sub> is equal to 78 [27 for Al + 17 x 3 for (OH)<sub>3</sub>], and that the mass of salt Al PO<sub>4</sub> is equal to 122 [27 for Al + 31 for P + 64 for O<sub>4</sub>], the quantities of these 2 compounds must be multiplied by the ratio 27/78, for aluminum hydroxide, and the ratio 27/122, for aluminum phosphate.

#### These details are worth remembering:

- for information, in the table of vaccines containing DTP which appears on the <u>website of the</u> <u>National League for Freedom of Vaccination</u>, and on the instructions for vaccines in which the quantities of aluminum are expressed in  $Al^{3+}$  ion;

- and for the attention of the members of the group of the National Academy of medicine, who wrote the article which appeared in the bulletin of the National Academy of medicine, because they did not take it into account (<u>Pierre BÉGUÉ</u>, Marc GIRARD, Hervé BAZIN, Jean-François BACH - Vaccine adjuvants: what's new in 2012? Bull. Acad. Natle Méd., 2012, 196,  $n \circ 6$ , 1177-1181, session of June 26, 2012).

# Gastric antacid drugs containing aluminum

In France, 6 drugs, gastric antacid dressings, containing aluminum, are marketed: MAALOX<sup>®</sup>, PHOSPHALUGEL<sup>®</sup>, MOXYDAR<sup>®</sup>, ROCGEL<sup>®</sup>, XOLAAM<sup>®</sup>, and SMECTA<sup>®</sup>. The toxic dose calculations were made for an adult weighing 60 kg.

# 1- MAALOX<sup>®</sup> (Sanofi)

## **COMPOSITION**

- Chewable tablets	per tablet
Aluminium hydroxide :	400 mg
Magnesium hydroxide :	400 mg
- Oral suspension in a bottle :	per tablespoon
Aluminium hydroxide :	525 mg
Magnesium hydroxide :	600 mg
- Oral suspension in sachet:	per sachet
Aluminium hydroxide :	460 mg
Magnesium hydroxide :	400 mg

<u>Dose regimen</u>: 1 to 2 tablets, or 1 tablespoon, or 1 to 2 sachets per dose at the time of gastric burns. Do not exceed 12 tablets per day, or 6 tablespoons per day or 12 sachets per day. Given the previous reminder, we deduce that:

- each MAALOX<sup>®</sup> tablet contains: 400 mg x 27/78 = 138.5 mg of aluminum metal, which, for a 60 kg man represents 138.5 mg / 60 kg = 2.31 mg of aluminum per kg body weight, corresponds to 2.3 times the minimum Toxic Dose per day defined by the FDA and WHO.

For the maximum authorized dose of 12 tablets per day, a 60 kg man will absorb: 2.3 x 12 = 27.6 times the minimum toxic dose per day.

- each tablespoon of MAALOX<sup>®</sup> or al suspension contains: 525 mg x 27/78 = 181.7 mg of aluminum metal, which, for a 60 kg man represents 181.73 mg / 60 kg = 3.03 mg aluminum per kg of body weight, corresponds to 3 times the minimum Toxic Dose per day defined by the FDA and WHO.

For the maximum authorized dosage, of 6 tablespoons per day, a 60 kg man will absorb 3 x 6 = 18 times the minimum toxic dose per day.

- each MAALOX<sup>®</sup> sachet contains: 460 mg x 27/78 = 159.2 mg of aluminum metal, which, for a 60 kg man represents 159.2 mg / 60 kg = 2.65 mg of aluminum per kg body weight, corresponds to 2.65 times the minimum Toxic Dose per day defined by the FDA and WHO.

For the maximum authorized dosage, of 6 sachets per day, a 60 kg man will absorb 2.65 x 6 = 16 times the minimum toxic dose per day.

# 2- PHOSPHALUGEL<sup>®</sup> (Astellas Pharma)

# COMPOSITION- Oral suspension in sachet-doseAluminum phosphate gel 20%- Oral suspension in bottleAluminum phosphate gel 20%2,476 g2,476 g2,476 g

Each sachet or tablespoon of PHOSPHALUGEL<sup>®</sup> contains: 2.476 g, or 2476 mg of aluminum phosphate, or 2476 mg x 27/122 = 548 mg of aluminum metal, which, for a man of 60 kg represents 548 mg / 60 kg = 9.13 mg of aluminum per kg of body weight, corresponds to 9.13 times the minimum toxic dose per day defined by the FDA and WHO.

For the maximum authorized dosage, of 6 sachets per day, or of 6 tablespoons, a man of 60 kg will absorb 9.13 x 6 = 55 times the minimum Toxic Dose per day.

# 3- MOXYDAR<sup>®</sup> (Grimberg)

#### **COMPOSITION**

- Tablets for oral suspension	per tablet
Hydrated aluminum oxide:	500 mg
Magnesium hydroxide:	500 mg
Aluminum phosphate:	300 mg
Coated guar gum:	200 mg

Taking into account the previous reminder, we deduce that **each MOXYDAR**<sup>®</sup> **tablet contains**: 500 mg x 27/78 = 173.1 mg of aluminum metal + 300 mg x 27/122 = 66.4 mg of aluminum metal, i.e. in total : 239.5 mg of aluminum metal, which, for a man of 60 kg represents 239.5 mg / 60 kg = 4 mg of aluminum per kg of body weight, corresponds to 4 times the minimum toxic dose per day defined by the FDA and WHO.

For the maximum authorized dose, of 4 tablets per day, a 60 kg man will absorb: 4 x 4 = 16 times the minimum toxic dose per day.

# 4- ROCGEL<sup>®</sup> (D & A Pharma)

#### **COMPOSITION**

- Sachets for oral suspension	per sachet
Hydrated aluminum oxide (boehmite),	
either aluminum oxide:	1212 mg

Given the previous reminder, we deduce that **each sachet of ROCGEL**<sup>®</sup> **contains** 1212 mg x 27/78 = 419.5 mg of aluminum metal, which, for a man of 60 kg represents 419.5 mg / 60 kg = 7 mg aluminum metal per kg of body weight, corresponds to <u>7 times the minimum toxic dose</u> **per day defined by the FDA and WHO.** 

For the maximum authorized dosage, of 6 sachets per day, a 60 kg man will absorb: 7 x 6 = 42 times the minimum toxic dose per day.

# 5- XOLAAM<sup>®</sup> (Ranbaxy Pharmacie Génériques)

## **COMPOSITION**

<ul> <li>Chewable or suckable tablets</li> <li>Aluminum hydroxide gel:</li> <li>Magnesium hydroxide gel:</li> </ul>	per tablet 400 mg 400 mg
- Oral suspension in a bottle:	per tablespoon
Aluminum hydroxide gel:	525 mg
Magnesium hydroxide gel:	600 mg

<u>Dose regimen</u>: 1 to 2 tablets, or 1 tablespoon, at the time of pain. Do not exceed 12 tablets per day, or 6 tablespoons per day.

Given the previous reminder, we deduce that:

- Each XOLAAM<sup>®</sup> tablet contains: 400 mg x 27/78 = 138.5 mg of aluminum metal, which for a 60 kg man represents 138.5 mg / 60 kg = 2.31 mg of aluminum per kg body weight, corresponds to 2.3 times the minimum toxic dose per day defined by the FDA and WHO.

For the maximum authorized dose of 12 tablets per day, a 60 kg man will absorb: 2.3 x 12 = 27.6 times the minimum toxic dose per day.

Each tablespoon of XOLAAM<sup>®</sup> oral suspension contains: 525 mg x 27/78 = 181.7 mg of aluminum metal, which for a 60 kg man represents 181.7 mg / 60 kg = 3.03 mg aluminum per kg of body weight, corresponds to <u>3 times the minimum toxic dose per day defined by the FDA and WHO.</u>

For the maximum authorized dosage, of 6 tablespoons per day, a 60 kg man will absorb:  $3 \times 6 = 18$  times the minimum toxic dose per day.

# 6- SMECTA<sup>®</sup> (Laboratoire Ipsen Consumer Healthcare)

The active ingredient in **SMECTA®** is diosmectite. One sachet of SMECTA® contains 3 gr. diosmectite, which is an aluminum and magnesium silicate. Its chemical formula is as follows: (https://en.wikipedia.org/wiki/Diosmectite):

## (Na-Ca)0,33 - (Al-Mg)2 - Si4 - O10 - (O-H)2 (H2 O)2

#### Calculation of the molar mass of diosmectite:

Atomic masses of diosmectite atoms:

- Al = 27 - If = 28.1 - Na = 23 - Ca = 40.1 - Mg = 24.3 - O = 16 - H = 1

**Diosmectite molar mass:**  $(23 + 40.1) \times 0.33 + (27 + 24.3) \times 2 + 28.1 \times 4 + 16 \times 10 + (16 + 1) \times 2 + (2 + 16) \times 2 = 469.2$ 

#### **Calculation of the amount of aluminum in a Smecta® sachet:**

Knowing that there are 2 atoms of Aluminum Al, that is 54, in a mole of diosmectite, and that there are 3 g of diosmectite per sachet of Smecta, we deduce that there are  $54 / 469.2 \times 3000 \text{ mg} = 345.3 \text{ mg}$  of aluminum metal per sachet

Knowing that the minimum Toxic Dose (minimal Risk Level) defined by the FDA and WHO, from 1989, is equal to 1 mg of Al metal / kg of body weight / day, it is obvious that: <u>the oral</u> intake of a single sachet of SMECTA<sup>®</sup> which contains 3 g of diosmectite, is much higher than the minimum toxic dose for children as well as for adults.

### **1- SMECTA<sup>®</sup> 3g strawberry:** Sachets for oral suspension

#### **COMPOSITION**

Diosmectite

per sachet 3 g.

Dosage regimen:

1) Treatment of acute diarrhea:

- Infant and child:

- before 1 year: 2 sachets per day for 3 days, then 1 sachet per day

- after 1 year: 4 sachets per day for 3 days, then 2 sachets per day

- Adults:

- 3 sachets per day on average. The dosage can be doubled at the start of treatment

2) Other indications:

Same dosages in children and adults as for the treatment of diarrhea

For the maximum authorized dosages, children will absorb more than 100 times the minimum toxic dose of aluminum per day, while an adult of 60 kg, will absorb between 17 and 35 times the minimum toxic dose of aluminum per day.

Note: Due to the fact that it is an aluminum salt of silicic acid, <u>the absorption of aluminum is probably much lower.</u>

2- SMECTA<sup>®</sup> 3g orange-vanilla : Powder for oral suspension

COMPOSITION Diosmectite per sachet 3 g.

Same dosages and indications as the SMECTA®-3g strawberry

## <u>Vaccines containing aluminum for newborns</u> (according to the manufacturers' sources)

Toxic dose calculations were performed for 5 kg infants

INFANRIX HEXA (GSK) Composition of the aluminum adjuvant: Aluminum hydroxide Aluminum phosphate Total :	Aluminum (ion Al <sup>3+</sup> ) 0,50 mg 0,32 mg <b>0,82mg</b>
HEXYON (Sanofi Pasteur) Composition of the aluminum adjuvant: Aluminum hydroxide Total :	<b>Aluminum (ion Al<sup>3+</sup>)</b> 0,60 mg <b>0,60 mg</b>
VAXELIS (MSD) Composition of the aluminum adjuvant: Aluminum hydroxide	<b>Aluminum (ion Al<sup>3+</sup>)</b> 0,60 mg

For an infant who weighs 5 kg, at the age of 2 months, at the time of his first vaccination, the dose of aluminum metal injected into his body should not be exceeded (according to the recommendations of the WHO and the FDA) is: 0.01 mg x 5 kg, i.e. 0.05 mg of aluminum.

0,60 mg

However, <u>from the age of 8 weeks</u>, <u>the 1st dose of one of the 3 hexavalent vaccines</u> brings to the body of the infant quantities <u>10 to 16 times higher than the minimum Toxic Dose</u> <u>decreed by the FDA and the WHO</u>. Which is, of course, formally prohibited by these health authorities.

Indeed :

Total :

#### 1) INFANRIX HEXA

This vaccine contains: - 0.50 mg of Al<sup>3+</sup> ion, administered in the form of aluminum hydroxide Al (OH)<sub>3</sub> - and 0.32 mg of Al<sup>3+</sup> ion, administered in the form of aluminum phosphate Al PO<sub>4</sub>.

Thus, the 1st dose of INFANRIX HEXA injects 0.82 mg of Al<sup>3+</sup> ion into the body, <u>which</u> is 16 times greater than the minimum toxic dose for a 5 kg infant.

## 2) HEXYON et VAXELIS

These vaccines contain 0.60 mg of Al<sup>3+</sup> ion administered as aluminum hydroxide Al (OH)<sub>3</sub>.

Thus the 1st dose of Hexyon or Vaxelis injects into the body 0.21 mg of Al<sup>3+</sup> ion, which is 10 times higher than the minimum toxic dose for a 5 kg infant.

And this is only the beginning, since, **during its 1st year**, **it will receive in its organism other vaccines containing aluminum adjuvants**, in the form of aluminum phosphate and aluminum hydroxide, as we are going to see.

## **Compositions of other compulsory vaccines, intended for infants, and which contain aluminum adjuvants**

#### **PREVENAR 13 (Pfizer)**

The Pneumococcus vaccine (13 serotypes), named PREVENAR 13, from the Pfizer Laboratory, contains 0.125 mg of  $Al^{3+}$  ion in the form of Aluminum phosphate Al PO<sub>4</sub>.

**NEISVAC (Pfizer)** or **MENJUGATE (GSK)** or **MENINGITEC (Nuron Biotech) The meningococcal C vaccine** (*Neisseria meningitidis*, serogroup C). These vaccines contain **0.30 to 0.40 mg of Al<sup>3+</sup> ion, administered as aluminum hydroxide Al(OH)**<sub>3</sub>.

For each dose, the infant receives in his body <u>0.30 to 0.40 mg</u> of  $Al^{3+}$  ion, <u>which is 6 to 8</u> times higher than the minimum Toxic Dose for an infant of 5 kg, which is added to the quantities provided to the body by other vaccines containing aluminum adjuvants.

Officially this vaccine will be imposed on infants aged 2 to 11 months, at the rate of 2 doses 2 months apart, and a booster during the second year of life, respecting an interval of at least 6 months after the 2nd dose.

<u>In total</u>, in application of the law of compulsory vaccination, a newborn, <u>from the age of 2 months</u>, <u>and during its first year</u>, will have received, at least, <u>2,775 mg to 3,635 mg of aluminum injected into its body</u>, a significant part of which will remain in his body for many years.

#### This breakdown is presented below:

- 3 or 4 times 0.60 to 0.82 mg = <u>1.80 to 2.46 mg of aluminum</u>, injected into his body in the form of hexavalent vaccines (INFANRIX HEXA, HEXYON, VAXELIS);

- 3 times 0.125 mg = 0.375 mg of aluminum, injected into his body in the form of pneumococcal vaccines (PREVENAR 13);

- 2 times 0.30 to 0.40 mg = 0.60 to 0.80 mg of aluminum, injected into his body in the form of meningococcal vaccines (NEISVAC, or MENJUGATE, or MENINGITEC).

Thus, from the age of 2 months, and during their first year of existence, <u>these children</u> <u>receive</u>, at least, 2,775 mg to 3,635 mg of aluminum, which represents, <u>for an average</u> weight of 7 kg, during their 1st year, <u>40 times to 52 times the Minimum Toxic Dose</u>.

# <u>Hepatitis B vaccines</u> intended for children and adults

## ENGERIX B 20 mcg (GSK)

This vaccine contains 0.50 mg of Al<sup>3+</sup> ion, administered as hydrated aluminum hydroxide Al(OH)<sub>3</sub>.

There are several administration schedules in 2 (children aged 11 to 15 years only), 3 or 4 injections between the 1st injection on a given date and 6 to 12 months, which corresponds to a total dose of aluminum injected included between 1 mg and 2 mg of aluminum.

In total, the dose injected into the body over a period of 6 to 12 months is very much higher than the minimum Risk Level, i.e. 0.01 mg of aluminum metal / kg of body weight / day, if we take into account the fact that a large neurotoxic fraction of the total dose of aluminum injected remains in the body for many years.

## **TWINRIX ENFANT (GSK)**

Inactivated hepatitis A and hepatitis B (rDNA) HAB vaccine, adsorbed.

#### It contains 0.225 mg of aluminum:

- 0.025 mg of Al<sup>3+</sup> ion administered in the form of aluminum hydroxide Al (OH)<sub>3</sub>;

- 0.200 mg of Al<sup>3+</sup> ion administered in the form of aluminum phosphate Al PO<sub>4</sub>.

**TWINRIX ENFANT** is indicated **for infants, children and adolescents aged 1 to 15 years**, not immunized against the hepatitis A and hepatitis B viruses, and identified as being at risk of infection by these viruses.

Usually, **the primary vaccination** with **TWINRIX ENFANT comprises 3 doses**, the first administered on day D0, the second 1 month later, and the third 6 months after the first injection.

In total, the vaccinated child will have received 0.450 mg of aluminum after one month, and 0.675 mg over a period of 6 months after the injection of the first dose, which is much higher than the minimum toxic dose.