

**Open Health**  
COMPANY

SURVEY ON THE ECONOMIC IMPACT RESULTING FROM THE UPDATING  
OF  
SWITCHES AND DE-REIMBURSEMENTS

Paris, March 3rd, 2016

David SYR  
Director of Surveys  
d.syr@openhealth.fr



1

•• Context and objectives

2

•• Methodology

3

•• Potential savings resulting from de-reimbursement

4

•• Potential savings resulting from switches

5

•• Synthesis

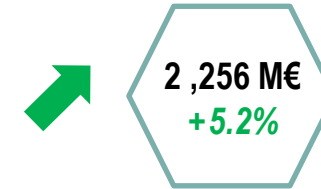
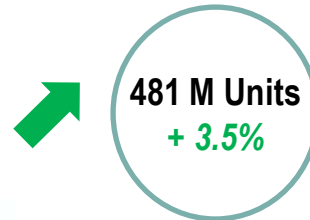
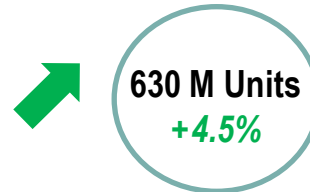
The Selfcare market **increased** during year 2015

Selfcare Market

Self-medication Market

**Volume of Sales**  
Units sold excluding prescriptions (consumer data)

**Value of Sales**  
excluding prescriptions in € (Retail price – Tax inclusive)



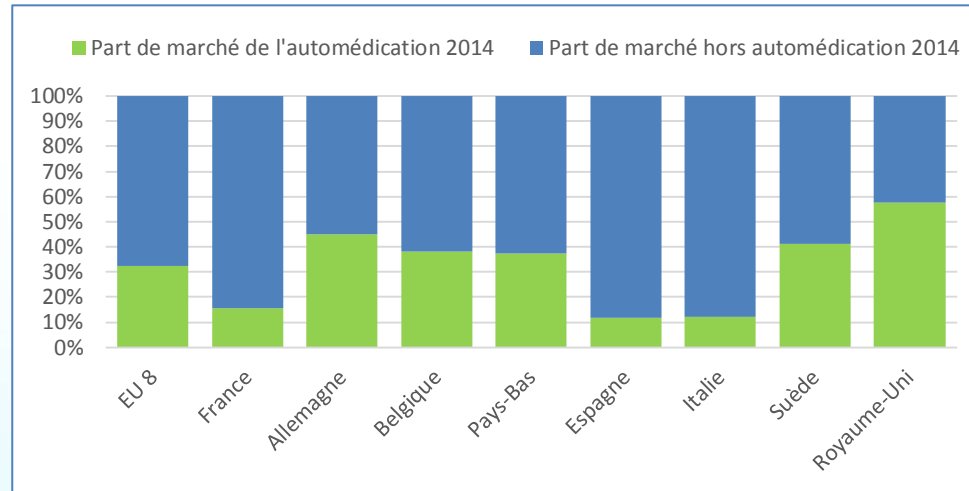
Several factors explain this increase in 2015:

- The successive pathology episodes and in particular the flu epidemic during T1 2015
- De-reimbursements: i.e. 27.7 M € of the 112 M € generated by market growth
- The increase in the number of people going to pharmacies: + 2.4%



- In spite of a dynamic year 2015, France is still **lagging behind** the other European countries:
  - Self-medication represents only **15.4%** of the volume of the French market, versus **32.3%** on average in the European countries assessed by the survey (Germany, Belgium, the Netherlands, Italy, Spain, the United Kingdom, Sweden).

### Volume of the self-medication market share in 2014



Source: AFIPA Survey - European Self-Medication Observatory 2014

- The progression potential remains significant with 35.3 € spent on self-medication per French person /per year versus 45.8 € spent on average in Europe.
- Thanks to **significant development potential** and a real **trend towards patients becoming more autonomous** in dealing with their own health, increasing the possibility of treating minor pathologies at pharmacy level becomes a major economic question.

Based on the list of indications / pathologies / clinical situations recognised as suitable for OMP\* use by ANSM and an AFIPA working group, the objectives were defined as follows:

- Define a scope of molecules subject to individual financing
  - Define a scope of molecules suitable for self-medication use and for which the tolerance profile is established and unquestioned.
- 
- **Measure the economic potential of the market development and the possible savings for the Mandatory Health Insurance resulting from the **de-reimbursement or complete switch of the molecules identified within each scope.****
  - **Measure the economic potential of the market development and the possible savings for the Mandatory Health Insurance resulting from the **de-reimbursement or switch of the molecules treating a single indication.****

\*OMP: Optional Medical Prescription

1

•• Context and objectives

2

•• **Methodology**

3

•• Potential savings resulting from de-reimbursement

4

•• Potential savings resulting from switches

5

•• Synthesis

## Based on the reference scopes ...

- List of the suitable indications/pathologies/clinical situations (ANSM)
- Completed with the indications proposed by the Afipa working group

## ...identification of the...

### De-reimbursable molecules

- Reimbursable MMP\*and OMP molecules :  
201 molecules – 66 indications
- Reimbursable MMP molecules :  
173 molecules – 66 indications

### Switchable molecules

- Tolerance profile established and unquestioned
- MMP molecules :  
118 molecules – 58 indications

+ Focus on the savings resulting from de-reimbursement and switches,  
clearly limited to the molecules treating a single indication

=

## Scope of the mono-indication molecules

15 indications

12 indications

\*MMP: Mandatory Medical Prescription

## Data sources

**6 718** pharmacies representative of the pharmacy network in France (mainland)<sup>1</sup>

**100 %** of the sales data

**100 %** of the references (180 000)

Reinforcement of precision

**CA > 2 M€**

Of which 3,054 pharmacies in the real-time-solution

Xpr-SO

Available in **D+1**

Information **on-line in real time**

**Dynamic extrapolation** and per data **quotas**<sup>2</sup>

They trust us



<sup>1</sup> Excluding Corsica

<sup>2</sup> Geographical location, total sales, structure of the total sales and implantation area



The economic model takes into account the following indicators :

- The potential savings are calculated for the mandatory schemes (including the exception schemes) and for 12 months of activity (2015).
- The amount of financing of a reference corresponds to the effective financing of the reference by the Mandatory Health Insurance based on the reimbursement rate of 15, 30, 65 or 100% in case of exemption of the patient's contribution: long-term health conditions (ALD, affections de longue durée), universal illness coverage (CMU, couverture maladie universelle), pregnancy, injury-on-duty, etc. This amount also includes the box fixed rate (0.80€).
- The average amount of financing of a private medical consultation (GP's + private practice specialists) is calculated based on the French National Health Insurance Fund for Employees data (CNAMTS, Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés) i.e. **18.85€ reimbursed per consultation**.
- Establishing a link between the number of private consultations and the number of sales in a pharmacy indicates that : **1 private practice consultation = 1.76 delivery of prescribed medicine in a pharmacy**

### **Only the direct costs are taken into account.**

The indirect costs (sick leave, reduced productivity) are not included due to the lack of reliable data estimating these costs.



✓ **Measure the possible collective savings** – within the Mandatory Health Insurance scope – **related to a de-reimbursement of the molecules** considered as suitable for OMP use.

2 scenarii are envisaged:

- Among the molecules on the list of indications / pathologies / clinical situations recognised as suitable for OMP use by ANSM completed by the AFIPA working group, identify which molecules are de-reimbursable

### Scenario 1

- Savings generated by the complete de-reimbursement of the de-reimbursable molecules **regardless of their indications for use**

### Scenario 2

- Savings generated by the de-reimbursement of the de-reimbursable molecules **delivered for indications subject to individual financing \***

\* See appendices

**Scenario 1:**

Estimate of the savings made in year 1

- Complete de-reimbursement of the reimbursable molecules delivered with or without a prescription, considered as suitable for OMP use regardless of their indications for use.

Savings on the financing  
of the references  
by the Mandatory Health Insurance

$\Sigma$  Amounts financed by the Mandatory Health Insurance  
for each of the references in 2015

Potential savings on the  
consultations  
(non-OTX\*)

Equivalent number\*\* of medical consultations\*\*\* avoided X  
Average financing by the Mandatory Health Insurance

\*OTX: Non-reimbursable OMP medicine

\*\* 1 medical consultation = 1.76 delivery of prescribed medicine in a pharmacy

\*\*\* Medical consultations: consultations by GP's and private practice doctors – Mainland France, source: French National Health Insurance Fund for Employees (CNAMTS, Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés)

**Scenario 2:**

Estimate of the savings made in year 1

- Complete de-reimbursement of the reimbursable molecules delivered with or without a prescription, and for which the indications for use are suitable for OMP use and subject to individual financing\*.

**Savings on the financing of the references by the Mandatory Health Insurance**

$$\sum \text{Amounts financed by the Mandatory Health Insurance for each of the references in 2015} \times \text{Ratio of the prescriptions delivered in private practices for indications subject to individual financing}$$

**Potential savings on the consultations (non-OTX\*)**

$$\text{Equivalent number** of medical consultations*** avoided} \times \text{Average financing by the Mandatory Health Insurance}$$

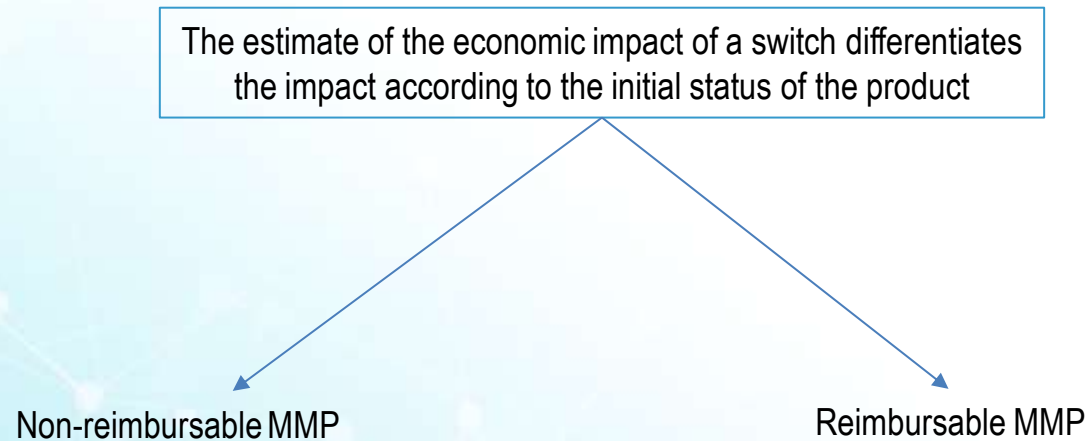
\* List of the suitable indications/pathologies/clinical situations (ANSM) completed with the indications proposed by the Afipa working group  
 \*\* 1 medical consultation = 1.76 delivery of the product with a prescription in a pharmacy  
 \*\*\* Medical consultations: consultations by GP's and private practice doctors – Mainland France, source: French National Health Insurance Fund for Employees (CNAMTS, Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés)



The model established in the framework of a complete switch of the molecules suitable for OMP use is defined based on 5 examples of molecules switched in the past in France.

These examples make it possible to model the impact on:

- The market dynamics following the switch of a molecule from MMP to OMP status in year 1 (in volume of sales)
- The reduction of the proportion of sales with a private practice medical prescription in year 1



The estimate of the savings made in year 1 is based on the complete switch of a molecule. In this case, delivering the products does not necessarily require a prior medical prescription. The switch results in de-reimbursement (if the prescription entitled the patient to obtain reimbursement).

Potential savings on the financing  
of the references  
by the Mandatory Health Insurance

$\sum$  Amounts financed by the Mandatory Health Insurance  
X Estimated number of deliveries with a prescription in year 1\*

Potential savings on the  
consultations

Average financing by the Mandatory Health Insurance  
X Equivalent number\*\* of medical consultations\*\*\* avoided

\*Calculation based on **the actual part prescribed in 2015, the market dynamics resulting from a switch and the estimated reduction of the volume delivered with a prescription in year 1**

\*\* 1 medical consultation = 1.76 delivery of the product with a prescription in a pharmacy

\*\*\* Medical consultations: consultations by GP's and private practice doctors –Mainland France, source: French National Health Insurance Fund for Employees (CNAMTS, Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés)

1

•• Context and objectives

2

•• Methodology

3

•• **Potential savings resulting from de-reimbursement**

4

•• Potential savings resulting from switches

5

•• Synthesis



## Scenario 1

Based on the indications suitable for OMP use according to ANSM completed by the AFIPA working group:

- The complete de-reimbursement of the molecules for which 15%, 30%, 65% or 100% are currently reimbursable in France, regardless of their indications for use, results in net potential savings of **2 794 million €** in year1.

These savings are split as follows: 20% on the medical consultations (GP's and private practice specialists) and 80% on the financing of the references.

### Potential savings resulting from the complete de-reimbursement of all molecules suitable for OMP use, regardless of the indication for use

	Potential savings on the consultations	Savings on the financing of the references by the Mandatory Health Insurance	Total
<b>Complete de-reimbursement</b>	551 936 139 €	2 242 182 095 €	<b>2 794 118 234 €</b>





## Scenario 2

Based on the indications suitable for OMP use according to ANSM completed by the AFIPA working group:

- The de-reimbursement of the molecules for indications considered as subject to individual financing\* and for which 15%, 30%, 65% or 100% are currently reimbursable in France, results in net potential savings of **1 538 million €** in year 1.

These savings are split as follows: 36% on the medical consultations (GP's and private practice specialists) and 64% on the financing of the references.

### Potential savings resulting from the de-reimbursement of the molecules suitable for OMP use and for which the indication for use is subject to individual financing

	Potential savings on the consultations	Savings on the financing of the references by the Mandatory Health Insurance	Total
<b>De-reimbursement on the framework of OMP indications</b>	551 936 139 €	986 545 381 €	<b>1 538 481 520 €</b>

\* List of the suitable indications/pathologies/clinical situations (ANSM) completed with the indications proposed by the Afipa working group



## Potential savings resulting from the de-reimbursement of molecules which exclusively treat a single indication\*

	Potential savings on the consultations	Savings on the financing of the references by the Mandatory Health insurance	Total
Minor and moderate stages of acne vulgaris	4 233 431 €	3 159 619 €	7 393 050 €
Heartburn, acid reflux	44 915 876 €	170 135 879 €	215 051 755 €
Local contraception, spermicides	766 785 €	30 793 886 €	31 560 671 €
Anesthetic cream – local application	7 974 196 €	33 281 030 €	41 255 226 €
Temporary (acute) diarrhea in adults	12 389 100 €	20 992 166 €	33 381 266 €
Earache, while waiting for medical advice	- €	328 659 €	328 659 €
Hypertriglyceridemia, hyperlipoproteinemia	10 760 658 €	45 796 403 €	56 557 061 €
Incontinence and ED (erectile dysfunction)	593 794 €	19 451 554 €	20 045 348 €
Nausea and vomiting	7 842 130 €	6 722 958 €	14 565 088 €
Localised Herpes labialis breakouts, also known as "fever blisters"	5 126 792 €	63 070 478 €	68 197 271 €
Prevention of cavities	80 543 €	1 306 916 €	1 387 458 €
Rosacea (topical treatment)	1 345 827 €	1 675 695 €	3 021 523 €
Dry mouth (xerostomia)	1 507 927 €	2 734 510 €	4 242 437 €
Dry coughs and coughs due to throat irritation (annoying, non-productive coughs) which began recently or not, in adults or children over 6 years of age (short-term treatment)	11 175 718 €	21 035 819 €	32 211 537 €
Treatment for prevention of osteoporosis, after initial medical advice	2 145 709 €	12 553 988 €	14 699 697 €

\*The indications mentioned are exclusively treated by mono-indication molecules

1

•• Context and objectives

2

•• Methodology

3

•• Potential savings resulting from de-reimbursement

4

•• **Potential savings resulting from switches**

5

•• Synthesis



Based on the indications suitable for OMP use according to ANSM completed by the AFIPA working group, the complete switch of the molecules which are currently not on Optional Medical Prescription in France results in net potential savings of **338 million €** in year 1.

The savings are split as follows: 70% on the medical consultations (GP's and private practice specialists) and 30% on the financing of the references. The results are detailed in the table below:

## Potential savings resulting from a complete switch of all molecules suitable for OMP use

	Potential savings on the consultations	Savings on the financing of the references by the Mandatory Health Insurance	Total
<b>Complete switch</b>	237 149 804 €	101 120 069 €	<b>338 269 873 €</b>



## Potential savings resulting from the switch of molecules which exclusively treat a single indication\*

	Potential savings on the consultations	Savings on the financing of the references by the Mandatory Health Insurance	Total
Minor and moderate stages of acne <b>vulagris (or vulgaris ?)</b>	1 128 375 €	92 745 €	<b>1 221 120 €</b>
Local contraception, spermicides	564 294 €	3 783 705 €	<b>4 347 999 €</b>
Anesthetic cream – local application	5 868 388 €	4 408 605 €	<b>10 276 993 €</b>
Haemorrhoidal crisis flare-up	356 046 €	311 €	<b>356 356 €</b>
Temporary (acute) diarrhea in adults	9 117 414 €	2 780 748 €	<b>11 898 162 €</b>
Hypertriglyceridemia, hyperlipoproteinemia	1 743 837 €	1 870 001 €	<b>3 613 838 €</b>
Incontinence and ED (erectile dysfunction)	3 333 327 €	4 875 €	<b>3 338 202 €</b>
Nausea and vomiting	7 782 €	81 €	<b>7 863 €</b>
Localised Herpes labialis breakouts, also known as "fever blisters"	3 772 920 €	8 354 694 €	<b>12 127 614 €</b>
Prevention of cavities	59 273 €	65 557 €	<b>124 830 €</b>
Rosacea (topical treatment)	23 699 €	- €	<b>23 699 €</b>
Dry coughs and coughs due to throat irritation (annoying, non-productive coughs) which began recently or not, in adults or children over 6 years of age (short-term treatment)	2 145 822 €	321 048 €	<b>2 466 869 €</b>

\*The indications mentioned are exclusively treated by mono-indication molecules

1

•• Context and objectives

2

•• Methodology

3

•• Potential savings resulting from de-reimbursement

4

•• Potential savings resulting from switches

5

•• **Synthesis**



### Identified scopes:

- 66 indications corresponding to 201 de-reimbursable MMP and OMP molecules and associations are identified
- 66 indications corresponding to 173 de-reimbursable MMP molecules and associations are identified
- 58 indications corresponding to 118 switchable molecules and molecule associations for which the tolerance profile is established and unquestioned.

### Potential savings generated in terms of medical consultations and financing of the references by the Mandatory Health Insurance:

- The hypothesis of a complete de-reimbursement of the molecules for which 15%, 30%, 65% or 100% are currently reimbursable in France results in net potential savings of **2 794 million €** in year 1, split as follows: 20% on the medical consultations\* (GP's and private practice specialists) and 80% on the financing of the references, i.e. respectively 552 million € and 2 242million €.
- The hypothesis of a de-reimbursement of the molecules for which 15%, 30%, 65% or 100% are currently reimbursable in France and which are used for indications subject exclusively to individual financing (indications suitable for OMP use) would result in net potential savings of **1 538 million €** in year 1, split as follows: 36% on the medical consultations (GP's and private practice specialists) and 64% on the financing of the references, i.e. respectively 552 million € and 986 million €.
- The hypothesis of a complete switch of the molecules which are currently not switched in France results in net potential savings of **338 million €** in year 1, split as follows: 30% on the financing of the references, with the balance of the potential savings corresponding to the costs estimated for the consultations\* during which these references were prescribed.

\* Without documented information regarding the purpose of the medical consultations, the estimate of the savings generated on the consultations avoided correspond to the potential and probably maximum savings on the consultations.





**Open Health**  
COMPANY

Thank you for your attention

[www.openhealth.fr](http://www.openhealth.fr)







# APPENDICES



## List of indications / pathologies / clinical recognised as suitable for OTC (Over-The-Counter) use by ANSM

### 1. Skin disorders

- Dandruff on adult scalp
- Localized Herpes labialis breakouts, also known as "fever blisters" or "cold sores"
- Antisepsis or cleaning of small, superficial skin wounds
- Nettle rash, insect bites, localized sunburn
- Skin irritation, notably due to diaper rash
- Moderate hair loss in adult males or females (androgenetic alopecia)
- Small, superficial burns
- Minor **and moderate (not in OpenHealth slide)** stages of *acne vulgaris* (*vulgaris* = manifeste, *quid vulgaris* ?)
- Sweat secretion disorders
- Moderate skin irritation, **including labial lesions from irritation (not in OpenHealth slide)**
- Skin dryness found with certain dermatoses
- Skin fissures, cracks, crevices
- Verrucas (local treatment) and warts
- Corns and calluses in adults, including between toes
- Intertrigo erythema between toes
- Lice and nits
- Localized outbreak of hives (itching, redness, edema)

### 2. Eye disorders

- Conjunctival irritation, single or repeat flare-ups
- Mild to moderate eye dryness
- Treatment for eye irritation (eye wash)
- Allergic conjunctivitis, seasonal or non-seasonal

### 3. Gastrointestinal disorders

- Temporary (acute) diarrhea in adults
- Abdominal bloating and gas
- Heartburn, acid reflux
- Occasional constipation in adults
- Nausea and vomiting (**without fever**) **not in Manifest**
- Dyspeptic disorders (slow digestion, bloating)
- Haemorrhoidal crisis flare-up
- Motion sickness
- Pinworms (small white worms in stools)
- Symptomatic treatment of pain **and intestinal discomfort (not in OpenHealth slide)** connected with functional disorders of the digestive and biliary tracts

### 4. Ear Nose and Throat (ENT) disorders

- Mild sore throat without fever (**bullet suivant Acute sore throat not in OpenHealth slide**)
- Throat irritation
- Stuffy nose (nasal blockage) / **nasal congestion not in OpenHealth slide**
- Clear nasal discharge
- Epistaxis (adjunctive treatment for occasional nosebleeds)
- Earache, while waiting for medical advice
- Rhinitis with purulent discharge but no fever, no facial pain and no headache
- Allergic rhinitis, seasonal or non-seasonal (clear nasal discharge, fits of sneezing, itching (pruritus) of nose and/or eyes): **hay fever not in OpenHealth slide**
- Treatment for adult colds : clear nasal discharge, headache and/or fever, stuffy nose

### 5. Upper respiratory tract disorders

- Dry coughs and coughs due to throat irritation (annoying, non-productive coughs), which began recently or not, in adults or children over 6 years of age (short-term treatment)
  - Difficult expectoration in adults (inability to spit out bronchial secretions effectively)
  - Bronchial secretion disorders (recent respiratory disorders with difficult expectoration) in adults
- Note : Coughs in children under 6 years of age require medical diagnosis and follow-up.

### 6. Dental disorders

- Small mouth wounds
- Canker sores, if fewer than 4 outbreaks per year
- Dry mouth (asialia)
- Prevention of cavities
- Pain from teething
- Oral hygiene
- Gingivitis in adults
- Postoperative care in dentistry
- Local adjunctive treatment for mouth infections, or postoperative care after mouth surgery



## List of indications / pathologies / clinical recognised as suitable for OTC (Over-The-Counter) use by ANSM

### 7. Gynaecological disorders

- Vulvovaginal fungal infections
- Local contraception, spermicides
- External cleansing and care of gynaecological area
- Painful menstruation

### 8. Circulatory disorders

- Functional manifestations of venous/lymphatic stasis : heavy legs
- Treatment of symptoms connected with venous/lymphatic stasis (heavy legs, pain, restless legs when patient first lies down...) not in OpenHealth slide
- Treatment of functional signs connected with haemorrhoidal crisis
- Mild trauma : ecchymosis, contusions (blows, bruises, bumps)

### 9. Rheumatic disorders

- Adjunctive therapy for posttraumatic edema
- Short-term local treatment for mild traumas : sprains, contusions
- Symptomatic treatment of painful OA (osteoarthritis) flare-ups, after at least one medical opinion *en italique dans Manifeste, devrait être slide 28 ?*
- Adjunctive treatment for pain involving muscles, tendons and ligaments
- Muscle cramps

### 10. Others

- Symptomatic treatment of painful and/or feverish conditions
- Medication indicated in case of pain and/or fever, occurring with headache, flu symptoms, toothache, muscle soreness, painful menstruation
- Migraine, after at least one medical opinion
- Smoking cessation (Manifeste n'indique que cela) / Temporary withdrawal from tobacco (pas dans Manifeste)
- Minor sleep disorders Manifeste indique 2 points: sleep disorders et minor sleep disorders / occasional insomnia
- Asthenia pas dans OpenHealth slide
- Temporary tiredness
- If several of the following symptoms occur together, it may point to a deficit in magnesium :
  - nervousness, irritability, mild anxiety, temporary tiredness, minor sleep disorders
  - symptoms of anxiety, such as digestive spasms or palpitations (healthy heart)
  - muscle cramps, tingling sensationsTaking magnesium may improve these symptoms.  
If symptoms do not improve after one month of treatment, it is useless to continue.

Pas dans Manifeste



## Indications considered as suitable for OTC (Over-The-Counter) use by the AFIPA working group

- Boils : **fusidic acid not in OpenHealth slide**
- Pityriasis versicolor
- Seborrhoeic dermatitis
- Seborrhoeic dermatitis on scalp
- **Minor and moderate stages of acne vulagris (??) => dans liste slide précédente, à retirer ici ?**
- Psoriasis (mild form)
- Rosacea (topical treatment)
- Photosensitive dermatosis (caused by sunlight)
- Chronic hives
- Eczema
- Sty, chalazion
- Bacterial Conjunctivitis (**risk of family contamination if left untreated or if there is no access to ophtalmologist**) **not in OpenHealth slide**
- Treatment for gastric and duodenal ulcers
- Acute sore throat **not in italics in Manifest, should be only in slide 26 ?**
- Symptomatic treatment of allergic symptoms associated with nasal congestion **not in italics in Manifest, should be only in slide 26 ?**
- Viral pharyngitis
- External ear infections in adults, after the pharmacist has checked eardrum integrity (**an otoscopic examination is mandatory**) **not in OpenHealth slide**
- Asthma crisis after initial medical advice
- Lower urinary tract infection in patients aged from 18 to 55 (cystitis)
- Benign prostatic hypertrophy
- Incontinence and ED (erectile dysfunction)
- Vaginitis
- Treatment of symptoms connected with venous/lymphatic stasis (heavy legs, pain, restless legs when patient first lies down ...) **not in italics in Manifest, should be only in slide 26 ?**
- Symptomatic treatment of painful OA (osteoarthritis) flare-ups, after at least one medical opinion **en italique dans Manifeste, mis en slide 27, devrait être slide 28 ?**
- Backache, acute lumbalgia
- Treatment for prevention of osteoporosis, after initial medical advice **not in italics in Manifest, should be added to slide 27 ?**
- Anesthetic cream – local application
- Muscle pain
- Hypertriglyceridemia, hyperlipoproteinemia
- **Manque toute la section Children, 6 points tous en italique dans Manifeste, rien dans OpenHealth slide, faut-il ajouter ? Mise à côté =>**

Itching associated with chickenpox, hives  
 Nauseae  
 Temporaty acute diarrhea  
 Dry cough  
 Oroductive cough  
 Infant regurgitation (with decision tree)