



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 August 2017

Prescribing of flupirtine in IMS Disease Analyser in Germany.

| | |
|------------------------------------|--|
| Substance | Flupirtine |
| Authorisation procedure | NAP |
| Procedure no | EMA/H/A-107i/1363 and EMA-H-N-PSR-J-0007 |
| PRAC Rapporteurs | Martin Huber (DE) |
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1. Rationale for review

On the 7th of March 2013 the European Medicines Agency (EMA) started a review under Article 107i of Directive 2001/83/EC of flupirtine-containing medicines used for short- and long-term pain relief¹ notified by the Federal Institute for Drugs and Medical Devices (BfArM).

The referral concluded by the EU Commission Decision on 5 September 2013 with the recommendations to initiate a PASS study, update the product information, and implement additional risk minimisation measures (e.g. educational material, DHPC) and additional pharmacovigilance activities (PASS and DUS).

Flupirtine-containing medicines are currently available in the following European Union (EU) Member States: Bulgaria, Estonia, Germany, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania and Slovakia.

2. Aim and objectives

The aim of this analysis is to provide prescribing information for flupirtine from IMS Disease Analyser in Germany.

¹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Flupirtine-containing_medicines/human_referral_prac_000019.jsp&mid=WC0b01ac05805c516f



3. Prescribing information in IMS Disease Analyser in Germany

Table 1: Events included in analysis

| | |
|--------------------|---|
| Date of analysis | 29/08/2017 |
| Substance | Flupirtine |
| Source country | Germany |
| Database | IMS Disease Analyser Germany version June 2017 |
| Events of interest | Total number of patients with a prescription for flupirtine by prescriber category Age and gender distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices Number of patients with a prescription for flupirtine and number of flupirtine prescriptions per halfyear and year in GP practices and orthopaedic practices between 1 January 2010 and 30 June 2017 Number of patients with a first prescription for flupirtine per halfyear and year in GP practices and orthopaedic practices between 1 January 2010 and 30 June 2017 |

3.1. IMS Disease Analyser in Germany

Anonymised patient medical records are collected since 1992 through a representative panel of internists (GPs and specialists in internal medicine) and other specialist physicians in computerized practices throughout Germany². The sampling of participating physicians is stratified for specialist group, region, and age of physician.

IMS Germany contains patient records including diagnoses, prescriptions, referrals, hospitalisations and sick notes. Risk factors such as BMI or smoking and laboratory values are also available as collected by the physicians.

The sampling of physicians ensures that patients may be considered as representative for the speciality of the physician over the different regions in Germany. In Germany, 83 % of practices are single physician practices. The rest of the practices have multiple physicians.

In Germany, patients are not listed with a GP. As patients do not need to register with a GP, the size of the patient population is not known. and needs to be estimated from the number of patients with an active consultation. The patient population of GPs in IMS Disease Analyser has been found to be broadly representative of the German population in terms of gender and age distribution, except for children.

² Becher H, Kostev K, Shröder-Bernhardi D. Validity and representativeness of the "Disease Analyzer" patient database for use in pharmacoepidemiological and pharmaco-economic studies. Int J Clin Pharmacol Ther 2009; 47 (10): 617-26.

In the IMS Disease Analyser databases, a unique ID is given to the patient at the level of the practice. If the same patient visits a different practice, a new ID is provided for the patient, which is not linked to the previous ID.

4. Results

4.1. Total number of patients with a prescription for flupirtine

A total of 199177 patients have been prescribed flupirtine (430682 prescriptions) in IMS Disease Analyser in Germany between 1992 (database start) and 30 June 2017:

- 134966 patients (317886 prescriptions) in GP practices (67.8% of all patients prescribed flupirtine)
- 50814 patients (80028 prescriptions) in orthopaedic practices (25.5% of all patients prescribed flupirtine)
- 7467 patients (20388 prescriptions) in neurologist practices (3.7% of all patients prescribed flupirtine)
- 4719 patients (10004 prescriptions) in internal medicine practices (2.4% of all patients prescribed flupirtine)
- 1211 patients (2386 prescriptions) in gynaecologist, ear-nose and throat, psychiatric, paediatric, urologist or dermatologist practices (0.6% of all patients prescribed flupirtine)

4.2. Age and gender distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices

The age distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices is shown in Figure 1. The gender distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices is shown in Figure 2.

Figure 1 Age distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices in IMS Disease Analyser in Germany

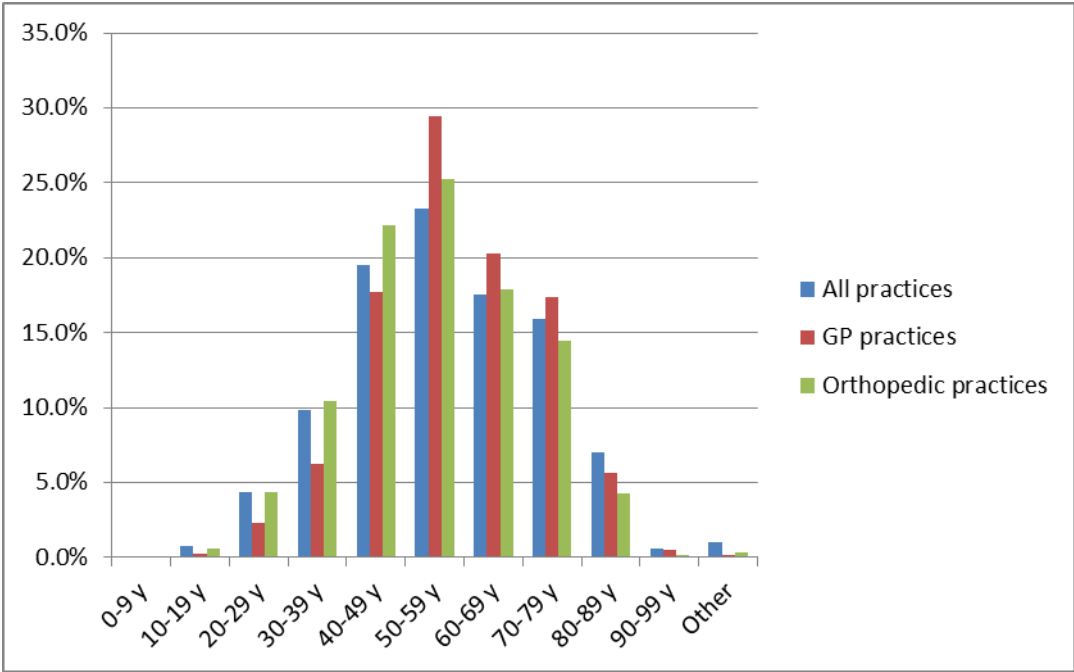
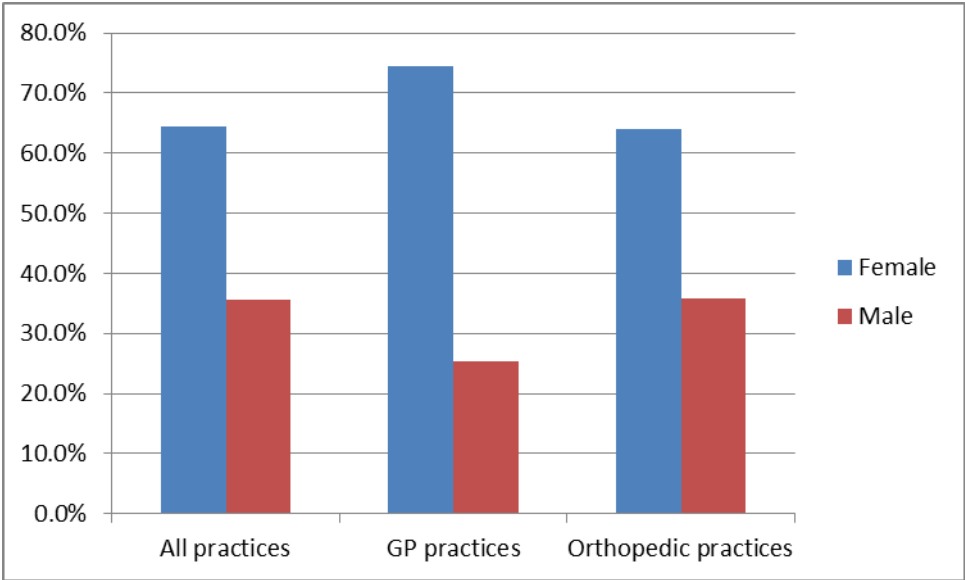


Figure 2 Gender distribution in all prescriptions for flupirtine, and in prescriptions for flupirtine from GP practices and orthopaedic practices in IMS Disease Analyser in Germany



4.3. Number of patients with a prescription for flupirtine and number of flupirtine prescriptions per halfyear and year

For the number of patients with a prescription for flupirtine and the number of flupirtine prescriptions per halfyear and year in GP and orthopaedic practices between 1 January 2010 and 30 June 2017, please see Table 1. The same information is also shown in Figure 3 for GP practices and in Figure 4 for orthopaedic practices.

Table 1: Number of patients with a prescription for flupirtine and number of flupirtine prescriptions between 1 January 2010 and 30 June 2017 in GP and orthopaedic practices in IMS Germany

| Time period | Number of patients in GP practices | Number of prescriptions in GP practices | Number of patients in orthopedic practices | Number of prescriptions in orthopedic practices |
|-------------------------------------|---|--|---|--|
| 1st halfyear 2010 | 7,439 | 11,950 | 3,003 | 3,745 |
| 2nd halfyear 2010 | 8,119 | 12,892 | 3,331 | 4,109 |
| 1st halfyear 2011 | 8,077 | 12,902 | 3,404 | 4,208 |
| 2nd halfyear 2011 | 9,969 | 15,764 | 3,750 | 4,649 |
| 1st halfyear 2012 | 10,549 | 16,201 | 3,780 | 4,663 |
| 2nd halfyear 2012 | 11,293 | 17,478 | 3,740 | 4,534 |
| 1st halfyear 2013 | 11,855 | 18,088 | 3,614 | 4,384 |
| 2nd halfyear 2013 | 10,457 | 14,699 | 2,729 | 3,232 |
| 1st halfyear 2014 | 8,824 | 12,478 | 2,582 | 2,997 |
| 2nd halfyear 2014 | 8,503 | 11,757 | 2,427 | 2,804 |
| 1st halfyear 2015 | 7,249 | 10,178 | 2,182 | 2,431 |
| 2nd halfyear 2015 | 6,677 | 9,379 | 2,091 | 2,341 |
| 1st halfyear 2016 | 6,068 | 8,433 | 2,085 | 2,365 |
| 2nd halfyear 2016 | 5,622 | 7,866 | 1,827 | 2,065 |
| 1st halfyear 2017 | 4,949 | 6,839 | 1,561 | 1,804 |
| 2010 | 13689 | 24,842 | 5904 | 7,854 |
| 2011 | 15875 | 28,666 | 6666 | 8,857 |
| 2012 | 19223 | 33,679 | 6988 | 9,197 |
| 2013 | 19816 | 32,787 | 5941 | 7,616 |
| 2014 | 15762 | 24,235 | 4759 | 5,801 |
| 2015 | 12671 | 19,557 | 4119 | 4,772 |
| 2016 | 10619 | 16,299 | 3740 | 4,430 |

Figure 3 Number of patients with a prescription for flupirtine and number of flupirtine prescriptions per halfyear in GP practices in IMS Disease Analyser in Germany

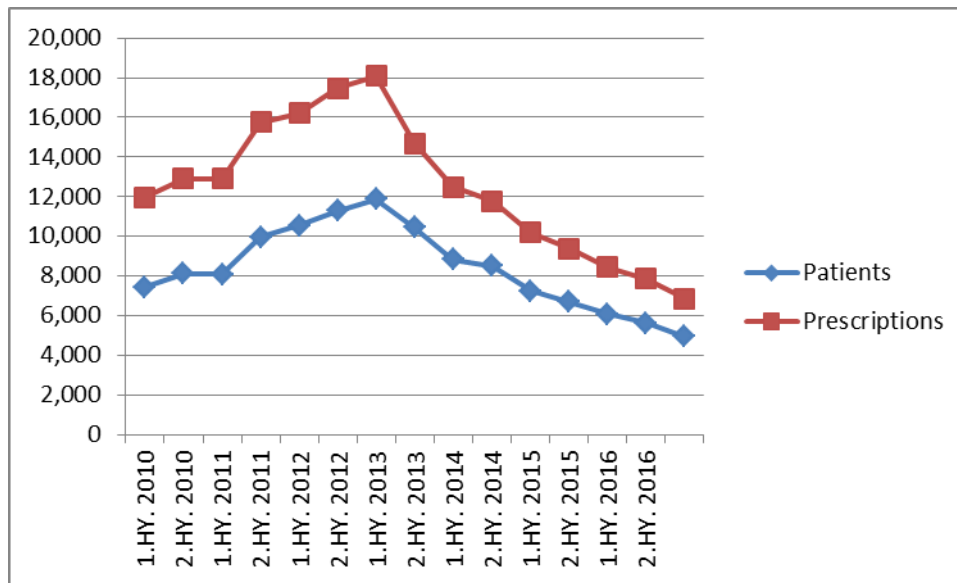
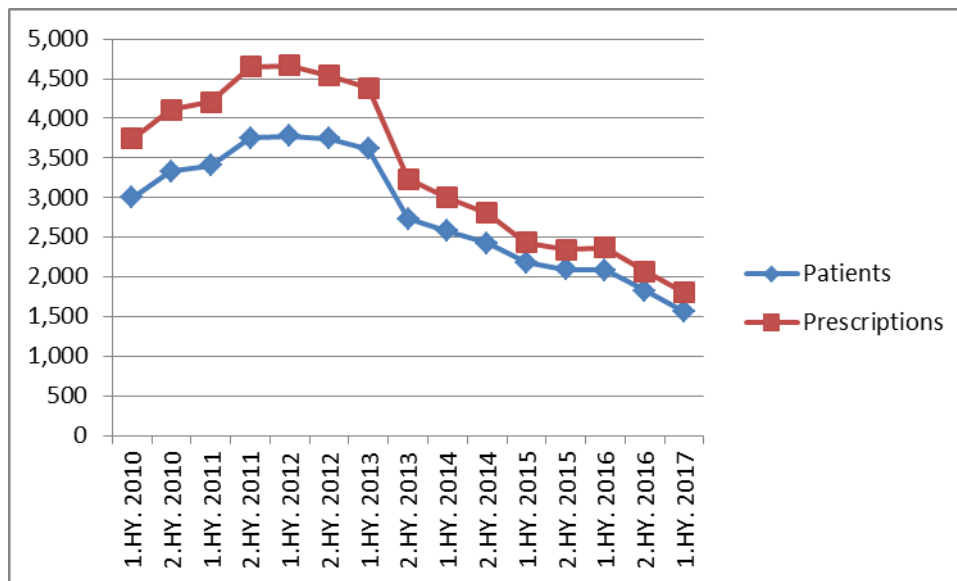


Figure 4 Number of patients with a prescription for flupirtine and number of flupirtine prescriptions per halfyear in orthopedic practices in IMS Disease Analyser in Germany



4.4. Number of patients with a first prescription for flupirtine per halfyear and year

For the number of patients with a first prescription for flupirtine per halfyear and year in GP and orthopaedic practices between 1 January 2010 and 30 June 2017, please see Table 2.

Table 2: Patients with a first prescription for flupirtine between 1 January 2010 and 30 June 2017 in GP and orthopaedic practices in IMS Germany

| Time period | Number of patients with a first prescription for flupirtine in GP practices | % of all patients with a flupirtine prescription in GP practices | Number of patients with a first prescription for flupirtine in orthopaedic practices | % of all patients with a flupirtine prescription in orthopaedic practices |
|-------------------------------------|--|---|---|--|
| 1st halfyear 2010 | 4,851 | 65.2% | 2,288 | 76.2% |
| 2nd halfyear 2010 | 5,201 | 64.1% | 2,571 | 77.2% |
| 1st halfyear 2011 | 5,057 | 62.6% | 2,614 | 76.8% |
| 2nd halfyear 2011 | 6,497 | 65.2% | 2,850 | 76.0% |
| 1st halfyear 2012 | 6,732 | 63.8% | 2,797 | 74.0% |
| 2nd halfyear 2012 | 7,230 | 64.0% | 2,791 | 74.6% |
| 1st halfyear 2013 | 7,473 | 63.0% | 2,754 | 76.2% |
| 2nd halfyear 2013 | 6,649 | 63.6% | 2,026 | 74.2% |
| 1st halfyear 2014 | 5,658 | 64.1% | 2,011 | 77.9% |
| 2nd halfyear 2014 | 5,509 | 64.8% | 1,905 | 78.5% |
| 1st halfyear 2015 | 4,494 | 62.0% | 1,738 | 79.7% |
| 2nd halfyear 2015 | 4,045 | 60.6% | 1,661 | 79.4% |
| 1st halfyear 2016 | 3,577 | 58.9% | 1,652 | 79.2% |
| 2nd halfyear 2016 | 3,379 | 60.1% | 1,426 | 78.1% |
| 1st halfyear 2017 | 2,878 | 58.2% | 1,149 | 73.6% |
| 2010 | 10,052 | 73.4% | 4,859 | 82.3% |
| 2011 | 11,554 | 72.8% | 5,464 | 82.0% |
| 2012 | 13,962 | 72.6% | 5,588 | 80.0% |
| 2013 | 14,122 | 71.3% | 4,780 | 80.5% |
| 2014 | 11,166 | 70.8% | 3,916 | 82.3% |
| 2015 | 8,539 | 67.4% | 3,399 | 82.5% |
| 2016 | 6,956 | 65.5% | 3,078 | 82.3% |