



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE SURGEON
GENERAL

JUN 4 2001

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|--------------------------|-------------|----------------|------------|
| MEMORANDUM FOR HQ ACC/SG | HQ AFIA/SG | HQ AFMC/SG | NGB/SG |
| HQ AFPC/DPAM | AFMSA/CC | HQ AFRC/SG | 311 HSW/CC |
| HQ AFSOC/SG | HQ AFSPC/SG | HQ AMC/SG | HQ AIA/SG |
| HQ AETC/SG | ANGRC/SG | HQ PACAF/SG | 11 MDG/CC |
| HQ USAFE/SG | HQ USAFA/SG | USAFSAM/CC/FEC | |

FROM: AFMOA/CC
110 Luke Avenue, Room 405
Bolling AFB, DC 20332-7050

SUBJECT: Use of Sonata® (Zaleplon) in Aviators and Special Duty Personnel

Effective immediately, the hypnotic Sonata® (Zaleplon) is approved for ground-based use by aviators and special duty personnel, in addition to Restoril® (Temazepam) and Ambien® (Zolpidem) within the USAF Fatigue Counter-measures Program. For the purposes of this policy memorandum, special duty personnel include members of Aeromedical Evacuation Teams and Critical Care Aeromedical Transport Teams.

Sonata® is a non-benzodiazepine pyrazolomopyrimidine hypnotic acting upon Gamma Amino-Butyric Acid (GABA) A1 receptors. The half-life of Sonata® is one hour and its pharmacodynamics, time to sleep onset, hangover and side effect profile compare favorably with the currently approved hypnotics, Restoril® (Temazepam) and Ambien® (Zolpidem).

The Ayerst-Wyeth™ preparation of Sonata® is approved as a single oral 10mg capsule dose taken immediately before sleep. The use of Sonata® is restricted to a maximum of 10 consecutive days and no more than 28 days in a 60-day period. The following ground testing procedures are to be undertaken:

- The "No-Go" pill overprint SF 600 at Attachment 1 is to be completed and enclosed in the individual's medical records.
- Individuals being ground tested must be placed in Duties Not Including Flying (DNIF) status.
- Results must be reviewed prior to Return To Flying Status but not earlier than 12 hours following test dose. Personnel reporting side effects should be evaluated immediately. Side effects are to be annotated on FDA Form 3500 and forwarded to the FDA Med Watch Program as directed and to MAJCOM/SG.
- AF Form 1042 (Medical Recommendations for Flying or Special Operational Duty) and DD Form 2766 (Adult Preventive and Chronic Care Flow sheet) are to be completed prior to operational No-Go Pill use.

My POC for this issue is Wing Commander Victor Wallace, AFMOA/SGZA, 110 Luke Avenue, Room 405, Bolling AFB, DC 20332-7050, DSN 297-4200, e-mail victor.wallace@usafsg.bolling.af.mil.



GARY H. MURRAY, Brig Gen, USAF, DC
Commander
Air Force Medical Operations Agency
Office of the Surgeon General

Attachment:
"No-Go Pill" Form 1

cc:
HQ USEUCOM/ECMD
USCENTCOM/CCSG

| | |
|----------------------|---|
| HEALTH RECORD | CHRONOLOGICAL RECORD OF MEDICAL CARE |
|----------------------|---|

DATE SYMPTOMS, DIAGNOSIS, TREATMENT, TREATING ORGANISATION *(Sign each entry)*

GROUND TESTING OF NO-GO PILLS - PART 1 - TESTING

| | | |
|---|------------------------------|---|
| Medically cleared for No-Go Pill ground testing based on focused history?: | Y <input type="checkbox"/> | N <input type="checkbox"/> |
| Instructions for ground testing fully explained: | Y <input type="checkbox"/> | N <input type="checkbox"/> |
| Script provided to patient:mg po at hs x 1 | Y <input type="checkbox"/> | N <input type="checkbox"/> |
| Patient advised to follow up next duty day, or sooner if unusual effects occur: | Y <input type="checkbox"/> | N <input type="checkbox"/> |
| AF Form 1042 signed - patient DNIF during ground testing period: | Y <input type="checkbox"/> | N <input type="checkbox"/> |
| Suspended from PRP; stamp completed? | N/A <input type="checkbox"/> | Y <input type="checkbox"/> N <input type="checkbox"/> |

.....
Flight Surgeon signature *Name* *Rank* *.....* *Date*

GROUND TESTING OF NO-GO PILLS - PART 2 - RESULTS

| | |
|---|---|
| NO-GO PILL: |mg |
| DATE INGESTED: TIME INGESTED: | |
| ADVERSE EFFECTS: Y <input type="checkbox"/> Complete FDA 3500 - MedWatch | N <input type="checkbox"/> |
| Comments: | |
| PATIENT SATISFIED WITH NO-GO PILL?: | Y <input type="checkbox"/> N <input type="checkbox"/> |
| CLEARED TO FLY, AF FORM 1042 COMPLETED AND SIGNED? | Y <input type="checkbox"/> N <input type="checkbox"/> |
| DD FORM 2766 UPDATED? | Y <input type="checkbox"/> N <input type="checkbox"/> |
| CLEARED FOR OPERATIONAL USE WITH NO EFFECT ON PRP STATUS? | Y <input type="checkbox"/> N <input type="checkbox"/> |

.....
Flight Surgeon signature *Name* *Rank* *.....* *Date*

| | | |
|---|-------------------------------|---------------|
| PATIENT'S IDENTIFICATION <i>(Use this space for Mechanical Imprint)</i> | RECORDS MAINTAINED AT: | |
| PATIENT'S NAME <i>(Last, first, Middle initial)</i> | | SEX |
| RELATIONSHIP TO SPONSOR | STATUS | RANK/GRADE |
| SPONSOR'S NAME | | ORGANIZATION |
| DEPART./SERVICE | SSN/IDENTIFICATION NO. | DATE OF BIRTH |

INSTRUCTIONS FOR USE

No-Go Pill Form 1 is a two-part form. Both parts need to be completed and signed for the patient to be certified to fly.

Part 1 records all pertinent information pertaining to an aircrew member prior to commencement of No-Go Pill ground testing. It acts as a checklist and must be completed prior to the issue of No-Go Pills. Focused history should center on current medications, alcohol usage and other potentially confounding diagnoses that would preclude a safe or valid ground test.

Aircrew will not fly and will be suspended from PRP status (if applicable) for 12 hours following ingestion of these medications.

Aircrew members should be advised to return on the next duty day, or sooner if unusual symptoms are experienced.

Part 2 documents the results of ground testing of No-Go Pills and must be completed following each ground test. Authorized medication and dosage should be noted and the patient cleared to fly for that specific medication and dosage (e.g. Temazepam 30mg).

If the aircrew member experiences any adverse effects during No Go Pill ground testing, an FDA Form 3500 – MedWatch should be completed and forwarded as directed. A copy of this form should also be forwarded to MAJCOM SG.

Each form should only be used for one No-Go Pill dosage level (e.g. Zolpidem 10mg). If new dosages or medications are to be tested, a new No-Go Pill Form 1 should be completed.

In addition to Parts 1 and 2 of No-Go Pill Form 1, the following forms must also be completed prior to final authorization of operational No-Go Pill usage, and before the individual is returned to flying duties following ground testing:

- AF Form 1042 (Medical Recommendations for Flying or Special Operational Duty)
- DD Form 2766 (Adult Preventive and Chronic Care Flowsheet)

The medication must also be cleared for operational use with no effect on PRP status (if applicable).

(Note: More medication options are expected in the near-term. Check current Air Force policy for the most current listing. It is recommended that crews be ground tested for each pharmacological approved by the Air Force in order to provide maximal operational flexibility for you to help them combat fatigue.)



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON, DC

MAR 30 1998

MEMORANDUM FOR HQ ACC/SG HQ AFIA/SG HQ AFMC/SG NGB/SG
HQ AFPC/DPAM HQ AFMSA/SG HQ AFRC/SG HSC/CC
HQ AFSOC/SG HQ AFSPC/SG HQ AMC/SG AL/AO
HQ AETC/SG ANGR/SG HQ PACAF/SG 11 MG/SG
HQ USAFE/SG HQ USAFA/SG USAFSAM/AF HQ AIA/SG

FROM: AFMOA/CC
110 Luke Avenue, Room 405
Bolling AFB DC 20332-7050

SUBJECT: Medical Policy Changes for USAF Air Crew

There has been some confusion as to the policy for the use of "No Go" pills in USAF aircrew members. Retroactive to January 1997, zolpidem is approved for use on the same basis as temazepam. The usual dose is 10 mg before bedtime. Single dose ground testing remains a requirement.

Specific operational use of "No Go" pills requires approval of the MAJCOM/SG. The MAJCOM/SG may delegate this to the flight surgeon at the operational unit where mission requirements make it difficult to obtain this approval in a timely fashion.

The use of temazepam or zolpidem is restricted to a maximum of 7 consecutive days and no more than 20 days in a 60 day period. Aviators will not fly for 12 hours after taking this medication. All flight surgeons prescribing these medications should be well versed in their potential side effects.

Two other medications are approved for use for all flying classes, with MAJCOM waiver authority, as of January 1998. These are loratadine and pravastatin. Loratadine is approved for use to treat seasonal allergic rhinitis. Members must have an initial 14 day DNIF period before waiver request. The maximum dose for loratadine is 10 mg daily. Pravastatin may be used on the same basis as lovastatin. This requires a 30 day DNIF prior to waiver request. Dosage will vary from 10 to 40 mg daily, depending on the therapeutic need.

My point of contact for these issues is Col Courtney Scott, AFMOA/SGOO, 110 Luke Avenue, Room 405, Bolling AFB, DC 20332-7050, DSN 297-4200.

Earl W. Mabry

EARL W. MABRY II, Maj Gen, USAF, MC
Commander
Air Force Medical Operations Agency
Office of the Surgeon General

cc:
HQ USEUCOM/ECMD
USCENTCOM/CCSG