## SHARED CARE PROTOCOL
For the use of Cyproterone Acetate (licensed for Hypersexuality);

Formulation types: Oral form (available in depot form on named patient basis)

BNF dose: 50mg BD (after food)

### SCOPE
Greater Manchester West Mental Health NHS Foundation Trust
Bolton Primary Care Trust
Salford Primary Care Trust
Trafford Primary Care Trusts

### Issue Date

### Author(s) Originator(s)
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*Thanks to:*
Prof Don Grubin, Dept of Forensic Psychiatry, St Nicholas Hospital, Gosforth, Newcastle
Joan Miller, BSTMHT, Pharmacy Dept.

### To be read in conjunction with the following documents
- Clinical Assessment letter on XXXX dated YYY
- BNF
- BST Document: A Treatment Strategy for the Use of Medication with Sexually Deviant
Any behavioural contract with XXXX

Offenders (Draft-2)
- Probation Circular PC35/2007 – Medical Treatment for Sex Offenders

Authorised by

Date

December 2007

Review Date
This protocol was reviewed in December 2007 following agreement of standards at the National Psychiatric Sex Offender Advisory Service Meeting on the 12th & 13th November 2007 in Newcastle

CLINICAL SUMMARY & OPINION

Clinical information on XXXX inserted here

CLINICAL RECOMMENDATION

Clinical recommendations on XXXX inserted here

CURRENT MEDICATION

Current medication on XXXX inserted here

1. Introduction
   This shared care protocol covers the for use of the oral anti-androgen, Cyproterone Acetate (Androcure) (BNF 6.4.2) (licensed for hypersexuality) for the treatment of male hypersexual and/or sexually deviant offenders

2. Scope
   Support for the use of these drugs comes from evidence obtained in clinical trials and case series.

   Cyproterone Acetate is the only medication licensed for male hypersexuality and sexual deviation in the UK.

   Treatment algorithm to ensure consistency.

   Medical treatment for sex offenders is entirely on a voluntary basis.

3. Clinical Condition Being Treated
   Men with recurrent intrusive sexual thoughts that they find distressing, or strong sexual urges that are difficult to control.
Men with hypersexual behaviour.

4. Product Information and Treatment Regimen to be Used

See Table-1.

5. Risk Management

Sexual & Non-Sexual Violence Risk
Risk assessment and management information on XXXX inserted here (preferably using Structured Clinical Judgement Tool eg. SVR20, RSVP, SARN)

Self Harm/Suicide Risk
Risk assessment and management information on XXXX inserted here

Substance Misuse Risk
Risk assessment and management information on XXXX inserted here

Other Risks
Risk assessment and management information on XXXX inserted here

Physical Health Risk
- List allergies here.
- Insert any history of major physical health problems here.
- Enquire about alcohol consumption (consumption of over 30U / week can induce liver enzymes and dose of Cyproterone Acetate may need to be increased).
- Enquire about Cardiovascular Risk (including family history) eg. Waist measurement, BP, Pulse, smoking status, hypercholesterolemia
- Physical Review for pre-existing gynaecomastia

Contraindications for Cyproterone Acetate (do not apply in prostate cancer):
- Hepatic disease
- Severe diabetes (with vascular changes)
- Sickle-cell anaemia (disease rather than trait)
- Malignant or wasting disease (transient catabolic effect)
- Severe depression
- History of thrombosis / embolism
- Youths under eighteen (may arrest bone maturation and testicular development)
- Metabolic bone disease

Side-Effects of Cyproterone Acetate:
More Common
- Fatigue & lassitude
- Breathlessness
- Weight change
- Reduced sebum production
- Changes in hair pattern
- Gynaecomastia and rarely galactorrhoea (usually commences after 6-12 months; risk of partial irreversibility from hyelinization & fibrosis. Consider discussion with an Endocrinologist - or Subareolar mastectomy if considered appropriate).
• Inhibition of spermatogenesis (reversible infertility – not to be relied upon for birth control)

Rarely
• Hypersensitivity reactions
• Rash
• Osteoporosis increased risk with higher dose and longer duration of treatment.
  (consider pre and continuing treatment with 70mg per week Alendronate, 400 units Vitamin D, 500mg Calcium)
• Hepatotoxicity

Consultant/Specialist Directorate SOTP Service

a. At the first interview, it must be clarified with XXXX whether he consents to a copy of his clinical assessment letter and information about ongoing progress being forwarded to both the referrer and his GP. Provided that the offender agrees, the expectation is that the psychiatrist will pass on relevant details regarding response to treatment, for example the impact of medication on fantasy content and frequency.

Because this is a medical setting, if an offender does not agree for information about him to be disclosed, then the psychiatrist will be limited in what can be communicated to confirming that the offender is attending (or is not attending) appointments, is taking medication, and a general statement about the effectiveness of the medication. However, this should be informed by the risk represented by the offender, and in higher risk cases it may be appropriate for more information to be disclosed (in which case the offender should be informed about what is being communicated).

If the offender does not agree to even this basic information exchange, then serious consideration will need to be given to not providing treatment.

Immediate and identifiable risk to others is paramount, and confidentiality should be overridden where this exists. Similarly, consideration should be given to breaching confidentially where there is an indication of an escalation in risk.

b. A pre-treatment assessment MUST be undertaken prior to treatment. This will include:
   i. Testosterone
   ii. FBC, U&E, LFT, RFT, Glucose, Lipid Screen
   iii.
   iv. Weight, BP, Pulse

c. Physical Health monitoring guidelines are summarised in Appendix 2. Preferably, such investigations will be undertaken within Primary Care and the results forwarded onto the SOTP Service.

d. After the initial assessment recommending treatment with anti-libidinal medication, XXXX will be provided with Patient Information leaflets so that he can give considered informed consent after the interview has taken place.

e. Clinical experience suggests that the desired effects of anti-androgens may not become apparent until three to four weeks after commencement of medication and are fully established at around six weeks.

f. To monitor response, tolerance and acceptability of treatment regularly even after prescribing is transferred over to Primary Care.
g. In normal circumstances, XXXX will be reviewed monthly by a Psychiatrist or Senior Nurse (experienced in anti-libidinal medical treatment). Frequency of follow up will be dependent on clinical and risk issues.

h. XXXX must be reviewed by a Psychiatrist experienced in anti-libidinal medical treatment at least yearly.

i. To inform GP and other appropriate agencies of XXXX's response to medication and general progress (by written correspondence). XXXX's GP and other appropriate agencies should be informed of any change in medication, or if medication is to be stopped (by written correspondence).

j. Current clinical opinion is that risk management is improved if medical treatment is integrated with psychological treatment, monitoring, general support and relapse prevention work. Whilst the patient is subject to license conditions, such risk management arrangements will fall under the remit of the Probation Service. If the patient is not subject to license or the license conditions are nearing the end, the patient would normally be offered a place (depending on appropriateness & availability within the service) in either the:
   i. SOTP Relapse Prevention Group
   ii. SOTP Treatment Group
   iii. Regular individual sessions with a worker from the SOTP Service.

k. The SOTP Service has no community team resources. There should be clear lines of communication for the communication of concerns between all agencies involved (with clear crisis contingency plans), preferably through MAPPA. In XXXX's case, any concerns about risk ought to be communicated to the following agencies:
   i. XXXX's Probation Officer – insert details here
   ii. District Manager for local area MAPPP – insert details here
   iii. Visor Unit – insert details here
   iv. Hostel Manager of the probation hostel – insert details here

l. These referrals will be subject to the SOTP CPA Policy and will either fall under either:
   i. The 'initial screening' section of the Trust CPA Policy (and not subject to the CPA framework) will be processed under Administrative Review (this will be different in different services).
   ii. Will be subject to Standard CPA.

m. If compliance with medication is a concern, then dispensing of medication by residential staffed may be considered (if appropriate). If medication is not dispensed, then recommendations for more frequent testing of testosterone levels may be indicated if there are concerns about compliance.

n. When patient is commenced on an antilibidinal, completion of a data sheet is required and this information is to be forwarded to Professor Grubin. See Appendix 6

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**General Practitioner**

a. To provide regular prescriptions for Cyproterone Acetate as per guidance from Specialist Services.

b. To be aware of the above-mentioned side effects profile.

c. Physical monitoring arrangements, as set out in Appendix-2
Psychology

Specify role of Forensic Psychologists (based with Probation Service)
Specify role of Clinical Psychologists (based with SOTP Service)
Consider undertaking a PCL-R for risk assessment purposes (if not already completed).
Consider XXXX’s need for:
   i. Relapse Prevention Group
   ii. Treatment Group
   iii. Regular individual sessions

MAPPA

a. XXXX is deemed level YYY MAPPP case
b. Sharing of information relating to risk.
c. To manage this group of offenders and to ensure the public is consistently and effectively protected from them.
d. Will form part of the Crisis Contingency Planning if XXXX is no longer subject to license conditions

Probation Service / Prison Service

Please refer to the document: “Probation Circular PC35/2007 – Medical Treatment for Sex Offenders”.

Offenders under community supervision should be identified via the offender manager. If identified by MAPPA, the offender manager should be advised in order that a referral is made. If the offender is in prison, the treatment manager for the prison SOTP may refer to the advisory service only after fully briefing the offender manager. If the offender is in prison but not subject to SOTP, the offender manager will need to liaise with the prison doctor before making such a referral. Such referrals will need the agreement of the offender before making such a referral bearing in mind the voluntary nature of the service.

Referral will be sent to the central point of contact in NOMS (National Offender Management Service) and will then be screened. Appropriate referrals will be sent to Professor Grubin (National Advisory Service: Medical Treatment for Sex Offenders, Northumberland Tyne & Wear NHS Trust) who will make the final decision regarding whether or not the referral is appropriate. If the referral is deemed appropriate, then Professor Grubin will discuss the case with the most appropriate local psychiatrist and inform the referrer of his or her identity so that they may liaise directly.

It should be noted that, in those areas where there are already established local medical services for sex offenders, the NOMS may make the referrals directly to that service without them requiring screening by Professor Grubin.

a. XXXX’s License Expiry Date is YYY
b. XXXX’s Sentence Expiry Date is YYY

c. There will be no statutory involvement of XXXX by Probation beyond YYY.
d. Probation is identified as the Primary Risk Management Agency whilst XXXX is subject to license conditions until YYY and Crisis Contingency Planning will fall primarily under their remit.

e. Probation Officer sessions will focus on: YYY.

7. Monitoring Arrangements

As this is a developing area, the profile of the phenomenology in these individuals will be scored pre-treatment to help identify whether certain profiles respond to particular treatment interventions.

Additionally, outcome measures will be used to assess the efficacy of the treatment (which will largely be based on self-report).

Outcome measures will include those agreed by the National Psychiatric Sex Offender Advisory Service (Appendix 5)

Additional profile and outcome measures may be designed by local Psychology colleagues and may cover the following domains: Sexual Preoccupation; Sexual Fantasies; Sexual Desire; Affective Symptoms; Obsessive-Compulsive Symptoms; Sexually Deviant Behaviour; Masturbation; Impulsivity; Aggression; Personality; Cognitive Function; User Satisfaction.

It is anticipated that this will help inform the Medical Treatment Algorithm.

Physical healthcare monitoring issues are summarised in Appendix 2 & 3.

8. Profile of Patients to be Treated

a. Men with recurrent intrusive sexual thoughts that they find distressing.
b. Men with hypersexual behaviour.
c. As these treatments are not guaranteed effectiveness, there is no proposal for them to be offered during criminal proceedings, i.e. as an alternative to prison sentence or linked to a Parole application.
d. Prescribing will be on a purely voluntary basis hence it should be established that patients might be willing in principle to take medication before they are seen.
e. Mild learning disability is not an exclusion criterion.

9. Written Information Provided to Patient

Information Leaflets will be provided.

10. Statement of Agreement Between GP and Consultant

This form is a request by the Consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care, please make this known to the Consultant within fourteen days, ideally stating nature of your concern.

11. Summary of Cautions, Contra-Indications and Side Effects

For cautions/contra-indications see BNF/SPC.
# APPENDIX-1

## Summary of Licensed Indications, Formulations and Dosage

<table>
<thead>
<tr>
<th>DRUG</th>
<th>LICENCED FOR</th>
<th>TYPICAL DOSAGE</th>
<th>FORMULATION</th>
<th>COST</th>
</tr>
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<tbody>
<tr>
<td>TRIPTORELIN</td>
<td>Advanced Prostrate Cancer</td>
<td>Decapeptyl SR – 3mg every 4 weeks.</td>
<td>IM Injection</td>
<td>Decapeptyl SR (powder for suspension)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gonapeptyl depot – 3.75mg every 4 weeks</td>
<td>S/C or deep IM injection</td>
<td>15mg vial (with diluent) = £207.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gonapeptyl depot 3.75mg pre-filled syringe = £85.00</td>
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<tr>
<td>GOSERELIN</td>
<td>Prostate Cancer, Advanced Breast Cancer</td>
<td>Zoladex – Goserelin 3.6mg in Safesystem syringe applicator every 28 days</td>
<td>S/C Implant</td>
<td>Zoladex – Goserelin 3.6mg in Safesystem syringe applicator = £84.14</td>
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<tr>
<td></td>
<td></td>
<td>Zoladex LA – Goserelin 10.8mg in Safesystem syringe applicator every 12 weeks</td>
<td>S/C Implant</td>
<td>Zoladex LA – Goserelin 10.8mg in Safesystem syringe applicator = £267.48</td>
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<td>LEUPRORELIN ACETATE</td>
<td>Advanced Prostrate Cancer</td>
<td>Prostap SR – 3.75mg every 4 weeks</td>
<td>S/C or deep IM injection</td>
<td>3.75mg vial with 1ml vehicle-filled syringe = £125.40</td>
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<tr>
<td></td>
<td></td>
<td>Prostap 3 – 11.25mg every 3 months</td>
<td>S/C Injection</td>
<td>11.25mg vial with 2ml vehicle-filled syringe = £376.20</td>
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<tr>
<td>CYPROTERONE ACETATE</td>
<td>Prostate Cancer</td>
<td>50mg BD after food</td>
<td>Tablets</td>
<td>Non-propriety 56 x 50mg tablets = £31.54</td>
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<tr>
<td></td>
<td>Severe male Hypersexuality</td>
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<td></td>
<td>Androcur 56 x 50mg tablets = £25.89</td>
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<tr>
<td></td>
<td>Male sexual deviation</td>
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APPENDIX-2

Recommendations for Initial Evaluation and Ongoing Monitoring in Patients

X for LHRH Agonists
Y for CPA

<table>
<thead>
<tr>
<th></th>
<th>Initial Visit</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>*Annually Thereafter</th>
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<td>Structured History about Metabolic Disorder</td>
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<td>Evidence of Gynaecomastia</td>
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</tr>
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<td>Testosterone</td>
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<td>XY</td>
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<td>XY</td>
<td></td>
<td>XY</td>
<td>XY</td>
<td></td>
</tr>
<tr>
<td>U&amp;E / RFT</td>
<td>XY</td>
<td>XY</td>
<td>XY</td>
<td>XY</td>
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</tr>
<tr>
<td>Glucose</td>
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<td>XY</td>
<td>XY</td>
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<td>TFT</td>
<td>XY</td>
<td></td>
<td>XY</td>
<td>XY</td>
<td></td>
</tr>
<tr>
<td>Lipids (not fasting)</td>
<td>XY</td>
<td>XY</td>
<td>XY</td>
<td>XY</td>
<td>XY</td>
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<tr>
<td>ECG</td>
<td>ICI</td>
<td></td>
<td></td>
<td>ICI</td>
<td>ICI</td>
</tr>
<tr>
<td>Specialised Bone Density Scan</td>
<td>X</td>
<td>ICI for Y</td>
<td></td>
<td></td>
<td>** X ICI for Y</td>
</tr>
</tbody>
</table>

(ICI) - If Clinical Indication

* After one year, investigations are carried out annually unless otherwise indicated
** Typically every 3 years, but may be more frequent in older men
## APPENDIX 3

PHYSICAL HEALTH MONITORING CHART FOR COMPLETION

### Pre-treatment

<table>
<thead>
<tr>
<th>Test</th>
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</thead>
<tbody>
<tr>
<td>full blood count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>liver function</td>
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<tr>
<td>glucose</td>
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<td>renal function</td>
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<td>lipids</td>
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<tr>
<td>testosterone</td>
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<td></td>
</tr>
<tr>
<td>weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bone density (GnRH agonist only)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical examination</td>
<td>*</td>
<td></td>
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</table>

*see separate notes

### Treatment

<table>
<thead>
<tr>
<th>Test</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>testosterone</td>
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<td></td>
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<tr>
<td>Bone density (GnRH only)</td>
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<td></td>
<td></td>
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<tr>
<td>weight</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>physical exam.</td>
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</tr>
</tbody>
</table>

*see separate notes*
THIS IS A GUIDANCE DOCUMENT ONLY FOR PRESCRIBING
CLINICIANS WILL CLEARLY PRESCRIBE MEDICATION BASED ON CLINICAL GROUNDS

if strong deviant fantasies / urges associated with distress / resistance
comorbid depressive, anxiety or obsessive-compulsive features
if CPA or LHRH indicated but patient finds such medication intolerable / unacceptable

Algorithm for the Pharmacological Treatment of Paraphilias

NOTE: LHRH = Luteinizing Hormone-Releasing Hormone Agonists. CPA = Cyproterone Acetate. SSRI = Selective Serotonin Reuptake Inhibitors.
Prescribing Protocol as agreed at the National Psychiatric Sex Offender Advisory Service Meeting, Newcastle in November 2007

We discussed prescribing protocols in respect of:

i. SSRI or anti-libidinal medication
ii. cyproterone of GnRH agonists

We agreed that existing protocols\(^1\) are over-dependent on risk as opposed to clinical indications, and that although risk needs to be taken into account, the starting point should be on clinical presentation. Based on our discussions, I am putting forward the following protocol for consideration:

1. Where mood state, sexual preoccupation, sexual rumination, or compulsive behaviour appears to be the main problem, start with SSRI:
   
   i. fluoxetine 20mg, increasing after 4 weeks to 40mg, and then after another 4 weeks to 60mg, depending on response
   
   or
   
   ii. sertraline 50mg, increasing to 100mg and 150mg at 4 week intervals depending on response
   
   iii. If initial SSRI ineffective, consider change to alternative SSRI, then cyproterone acetate 100mg a day

2. Where subjective sexual drive is exceptionally strong, or where fantasies/urges are associated with particularly high risk behaviours, start with anti-libidinal medication:

   • where compliance is not a major issue (bearing in mind that the medication is being taken voluntarily in all instances)
   
   i. cyproterone acetate 100mg, increased to 150mg after 8 weeks if little or partial effect, and then to 200mg after a further 8 weeks
   
   ii. if cyproterone ineffective, or side effects intolerable, switch to GnRH agonist

   • where compliance may be an issue (because offender may miss doses, or motivation is variable)
   
   i. start with depot cyproterone or a GnRH agonist (tryptorelin, goserelin, or leuprorelin on a 4 week schedule, titrating according to response

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\(^1\) The reference to 'existing protocols' and the mention of 'SSRI or anti-libidinal medication' and 'cyproterone of GnRH agonists' indicate previous discussions or protocols that exist, but the specific details of these protocols are not provided in the text.
# APPENDIX 5

**sexual behaviours during the week prior to this review**

<table>
<thead>
<tr>
<th>name of patient</th>
<th>date of review</th>
</tr>
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<tbody>
<tr>
<td>________________</td>
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<table>
<thead>
<tr>
<th>medication</th>
<th>dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>________________</td>
<td>________________</td>
</tr>
</tbody>
</table>

- Number of days masturbated leading to organism ________
- Number of days masturbated *not* leading to organism ________
- Number of days engaged in sexual behaviour with partner leading to orgasm ________
- Number of days engaging in sexual behaviour with partner *not* leading to orgasm ________
- Number of days engaged in any type of sexual behaviour on more than one occasion ________
- Maximum number of times engaged in sexual activity in any one day ________
Side effects reported:
APPENDIX 6

Database Information

*Draft 1*

Patient ID (last name of psychiatrist + number)

Setting
   (prison, community probation, community NHS, other)

Referral source
   (GP, psychiatrist, psychologist, probation officer, self, other)

Date of Assessment

Age at time of assessment

Sex Offending history
   number of convictions
   offences against children (Y/N)
   offences against adults (Y/N)
   non-contact offences (Y/N)

   brief summary

Medication start date

Drug
   name
   starting dose
   maintenance dose

Clinical response
   (good, none, negative)

   brief summary

Side effects

*Medication stop date*

Other comments